



**Mindfulness-Based Cognitive Therapy for People with
Depression and Cardiovascular Disorders:
The Heart and Living Mindfully (HeLM) Project**

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Abstract

Clinical depression is a chronic and comorbid condition with cardiovascular disorders (CVDs), with its presence leading to worse medical outcomes, higher rates of mortality, poor quality of life, poor adherence to treatment, and high health care costs. Psychological factors, such as higher rumination and health related worry and lower self-efficacy and self-care have been found to be associated with both conditions. As a result, it has been suggested that any psychological intervention aiming to treat comorbid depression in CVDs needs to target these factors.

Mindfulness-based cognitive therapy (MBCT) is a mind-body treatment that has shown promising effects in a wide range of physical conditions, with small to medium effect sizes. However, whether MBCT can help manage comorbid depression in CVD populations remains unclear. Therefore, the Heart and Living Mindfully (HeLM) project was developed to explore this issue. We developed a bespoke MBCT for people with comorbid depression and CVD through three phases. The first phase involved establishing the evidence base for developing the manual through conducting a systematic review and secondary analysis. The second phase pertained to conducting a pilot group for modifying the manual and checking its acceptability. The third and last phase was a feasibility randomised controlled trial (RCT) to uncover uncertainties around the MBCT-HeLM before proceeding with a definitive trial.

Overall, the three phases were successful and achieved their goals. The feasibility RCT provided useful information for future studies in terms of using a 3-arm design, recruitment, attrition and retention. The key learning point was that it was challenging to recruit a sufficient number of people into the trial, suggesting future research will need to develop alternative recruitment procedures to be feasible.

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Chapter 1.0

Literature Review

1.1 Introduction

Cardiovascular disorders (CVDs) are the main causes of mortality and morbidity in the UK. Clinical depression is a chronic and comorbid condition with CVDs, with its presence leading to worse medical outcomes and poor adherence to treatment. This chapter provides a comprehensive review of depression and cardiovascular disorders. First, how common these disorders are in the UK, the consequences of comorbidity between depression and CVDs, and the underlying links between these conditions are reviewed. Second, how depression has been measured and treated in the context of CVDs is discussed, highlighting the need for innovative treatments that both address acute and residual symptoms and prevent depressive relapse. Third, mindfulness-based cognitive therapy (MBCT) as a potential treatment is considered. Fourth, the need for developing a bespoke MBCT course for comorbid depression and CVDs is discussed. Finally, an overview of the other chapters in this thesis that aim to develop and evaluate such an approach is provided.

1.2 Depression and Cardiovascular Disorders (CVDs)

1.2.1 Depression.

Depression affects 350 million people, with it being the second most prevalent cause of disability-adjusted life years worldwide (World Health Organization, 2012). In the UK, 10.2 million people suffer from mental health problems, and depression is one of the most prevalent (Naylor et al., 2012). Major depressive disorder (MDD), as the most common of the depressive disorders, is characterised by one or more major depressive episodes (MDEs). An MDE is defined as the presence of between five and nine specified depressive symptoms for a period of at least two weeks, with one of

these being either depressed mood or loss of interest or pleasure (DSM-5, 2013, p. 160). The seven other symptoms of are: significant weight loss, insomnia or hypersomnia, psychomotoric agitation or retardation, fatigue or loss of energy, feelings of worthlessness or excessive or inappropriate guilt, decreased ability to think or concentrate and recurrent thoughts of death (DSM-5, 2013, p. 161).

Major depressive disorder (MDD) often follows a chronic relapsing course, with approximately 80 % of people with it having another episode (Judd, 1997). A review of 27 studies found that the recurrence of major depression in clinical settings was 60 % to 85 % over the following five to 15 years (Hardeveld, Spijker, De Graaf, Nolen & Beekman, 2010). Higher relapse rates have been found in those with a higher number of previous episodes, greater comorbidity, and greater severity of depression (Kennedy & Paykel, 2004; Melartin et al., 2004; Paykel et al., 1995). Even if individuals do not relapse, they are often left with residual symptoms. Up to 32 % of individuals suffer from residual symptoms in the first 15 months after an acute episode (Paykel et al., 1995) and this predicts difficulties in marital, social and work functioning (Kennedy & Paykel, 2004).

Other depressive disorders are minor depression and dysthymia, being called subthreshold depressive symptoms. Minor depression¹, which is categorised in Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) under depressive disorder not otherwise specified, is defined as the presence of two to four of the nine depressive symptoms for at least two weeks, with one of these being either depressed mood or loss of interest or pleasure (DSM-IV-TR, 2000, p. 777). Dysthymia (persistent depressive disorder) is characterised by a chronic depressed mood that occurs on most days for a period of at least two years. During this

¹ Note. "Minor depression" is not mentioned in DSM-5.

period, there is the presence of two or more of the following symptoms: poor appetite or overeating, insomnia or hypersomnia, low energy or fatigue, low self-esteem, poor concentration and feelings of hopelessness (DSM-5, 2013, p. 168). Whilst minor depression and dysthymia comprise symptoms that do not meet the criteria for MDD, they can cause very significant impairment in various aspects of a person's life. For example, dysthymia is by definition a chronic disorder, with estimates of 73 % of people with the condition requiring at least 52 months to recover (Klein, Shankman, & Rose, 2006). It has also been found to be related to a high risk of relapse (Klein et al., 2006).

Depression alone causes long-lasting suffering, substantial disability and a low quality of life (National Institute for Health and Care Excellence, 2009). This picture is exacerbated when it comes with a physical condition like cardiovascular disorders (CVDs) and according to the World Health Organization (WHO), depression and CVDs will be the main cause of morbidity worldwide by the year 2020 (Murray & Lopez, 1997).

1.2.2 Cardiovascular disorders (CVDs).

Cardiovascular disorders (CVDs) refer to the diseases that affect the heart and blood vessels (Mendis, Puska, & Norrving, 2011). There are different types of CVDs, such as cerebrovascular disease (e.g., stroke), diseases of the aorta and arteries (e.g., hypertension), peripheral vascular disease, congenital heart disease, rheumatic heart disease, cardiomyopathies and coronary heart disease (CHD) (e.g., myocardial infarction (heart attack), angina and heart failure). For example, coronary heart disease (CHD) (sometimes called coronary artery disease or ischemic heart disease) refers to “diseases that occur when the walls of the coronary arteries become narrowed by a

gradual build-up of fatty material called atheroma” (HFA, Townsend, Williams, Bhatnagar, Wickramasinghe & Rayner, 2014, p. 10).

CVDs have been the leading cause of morbidity and mortality in the UK since 1961 (Naylor et al., 2012). According to the heart foundation association (HFA), CVDs caused 28% of all deaths in the UK in 2012. Of these CVD related deaths, 46 % were due to coronary heart disease (CHD), while 15 % were due to stroke. Moreover, approximately 1.6 million people were admitted to hospital due to one or more cardiovascular events, including heart attacks or strokes (HFA, Townsend, Williams, Bhatnagar, Wickramasinghe & Rayner, 2014).

There is strong evidence for certain key risk factors of CVDs, including hypertension (high blood pressure), smoking, obesity and blood cholesterol, which are often triggered by unhealthy diet, physical inactivity and negative illness perceptions. For example, high blood pressure is considered as an important risk factor for developing a cardiovascular disorder (Kelly & Fuster, 2010). In a contemporary cohort study of 1.25 million people, it emerged that high blood pressure was significantly associated with a wide range of CVDs, such as angina, heart failure and cardiac arrest (Rapsomaniki et al., 2014). Hypertension (high blood pressure) is well-known as a resistant (difficult to treat) condition. A cross-sectional observational study in 12 European countries ($n = 5,222$) found that half of people treated for hypertension continued with high blood pressure, with approximately 14 % of them having resistant hypertension (Borghi et al., 2016). A systematic review of 147 studies covering 464,000 people with a history of CHD, stroke or no history of cardiovascular disorders suggested that reducing blood pressure is crucial to the prevention of CVDs (Law, Morris & Wald, 2009).

1.2.3 Comorbidity between depression and CVDs.

There is evidence that depression is two to three times more common in a wide range of CVDs compared with the healthy population (Naylor et al., 2012). It has been estimated that 15 % to 20 % of people with coronary heart disease (CHD) suffer from a major depressive disorder (MDD), while between 30 % to 50 % suffer from minor depression (Davidson, 2012; Huffman et al., 2013; Thombs et al., 2006).

Approximately 47 % of people with CHD have significant depressive symptoms that do not meet the criteria of MDD (Stewart, Ricci, Chee, Hahn & Morganstein, 2003).

Moreover, evidence suggests that the relationship between mental health and cardiovascular disorders is bidirectional (Baune et al., 2012; Khawaja, Westermeyer, Gajwani & Feinstein, 2009). This means that people suffering from mental health conditions are more likely to develop cardiovascular problems and vice versa.

Regarding which, empirical research has indicated that people with mental health problems, such as depression, anxiety, stress and bipolar disorder, are at a higher risk of cardiovascular morbidity and mortality compared to the healthy population (Colton & Manderscheid, 2006; DE Hert et al., 2011; Sowden & Huffman, 2009). These findings are supported by different systematic reviews that found that depression is an independent risk factor, with an estimate that it doubles the risk of the development and progression of cardiovascular disorders (Huffman, Celano, Beach, Motiwala & Januzzi, 2013; Lett et al., 2004; Lichtman et al., 2008; Van der Kooy et al., 2007).

Other mental health problems, such as anxiety and stress, are very common in people with cardiovascular disorders (Goodwin, Davidson & Keyes, 2009). A meta-analysis of 20 longitudinal studies suggested that anxiety is a risk factor for coronary

heart disease (CHD) (hazard ratio (HR): 1.26²) and cardiac mortality (hazard ratio (HR): 1.48³) (Roest, Martens, de Jonge & Denollet, 2010).

1.2.4 Consequences of comorbidity.

1.2.4.1 Mortality rate. Existing evidence shows that the comorbidity between depression and CVDs is associated with worse medical outcomes, including increased mortality rate. Ariyo et al. (2000) conducted a cardiovascular health study over six-years of follow up to examine the relationship between depression and the development of coronary heart disease (CHD) and cardiovascular mortality in elderly people ($n = 5,888$), who were without cardiovascular disorders at baseline. After adjustment for some cardiac risk factors, including diabetes, hypertension, stroke, antidepressant medication usage and smoking, the authors found that depression, as assessed by the Center for Epidemiological Studies-Depression Scale, was a risk factor of the development of CHD (adjusted odds ratio⁴: 1.15) and for all-cause mortality (adjusted odds ratio: 1.16). Parashar et al. (2006) conducted a study aimed at determining the association between acute myocardial infarction (MI) and depression. The study assessed 2,498 people with MI, of which 2,096 were eligible for this study, and categorised people with depression at baseline only (transient), at 1-month (new) or at baseline and 1-month (persistent) using the Patient Health Questionnaire-9 (PHQ-9). The adjusted hazard ratios (adjusted-HR⁵) for rehospitalisation or mortality were higher in people with depression ($n = 499$) with an adjusted hazard ratio of 1.34 for transient

² A hazard ratio of 1.26 here means that people with anxiety are 1.26 times as likely to develop coronary heart disease compared to those without.

³ A hazard ratio of 1.48 here means that people with anxiety are 1.48 times as likely to die for cardiac reason compared to those without.

⁴ Odds ratio is usually used with case-control, cross-sectional and cohort study designs.

⁵ Hazard ratio is usually used with survival analysis.

depression, 1.71 for new and 1.42 for persistent compared to those without depression ($n = 1,382$).

The hazard ratios reported in Airyo et al. (2000) and Parashar et al. (2006) are lower than those reported in a five years study by Lespérance, Frasure-Smith, Talajic & Bourassa (2002). This study was aimed to examining the effects of baseline depression at rehospitalisation and mortality in people with acute myocardial infarction (MI). The adjusted hazard ratios (HR) for rehospitalisation or mortality were higher in people with depression, with an HR of 3.17 for moderate depression, and 3.13 for those with severe depression compared to those without depression. The study cohort was adjusted for age, gender, diabetes and smoking, with depression being assessed by the Beck depression inventory (BDI).

In the previous studies, there is inconsistency regarding the reported adjusted hazard ratios for mortality arising from depression, which could be due to the use of self-reported measures of depression and measuring depression at baseline only. There are also limitations resulting from the heterogeneity of heart conditions, mortality causes and follow-up length. Nevertheless, van Melle et al. (2004) and Meijer et al. (2011) conducted meta-analyses of studies that considered the association between depression and mortality rate in myocardial infarction (MI) population and found that the pooled odds ratio for cardiac and all-cause mortality ranged between 2 and 2.5.

1.2.4.2 Non-adherence and hospitalisation. Importantly, evidence also suggests that depression is associated with poor cardiac or psychiatric medication adherence in the context of CVD, which leads to poor treatment outcomes. A number of systematic reviews have shown that people with cardiac problems, with a major depressive disorder (MDD) or dysthymia, are likely to have a high non-adherence to their medication (cardiac or antidepressant) and completion of cardiac rehabilitation

programmes (Joynt, Whellan & Connor, 2004; Khawaja et al., 2009; Naylor et al., 2012; Rustad, Stern, Hebert & Musselman, 2013). Depression has also related to increasing hospital admission rates, the use of health services by people with coronary artery disease (Baumeister, Haschke, Munzinger, Hutter & Tully, 2015) and increased emergency admission rates for people with CVDs (Naylor et al., 2012; Rustad, Stern, Hebert & Musselman, 2013).

1.2.4.3 Quality of life. Depression is related to the quality of life for people with cardiovascular disorders. Quality of life refers to “individuals’ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” (WHO, 1998, p. 1). A prospective study (de Jonge, Spijkerman, van den Brink & Ormel, 2006) with a 12-months follow-up showed that people with depression had poorer quality of life and higher health and cardiac complaints compared to people without, for those who had experienced a myocardial infarction (MI). Cerniauskaite et al. (2012) conducted a study of disability and quality of life in people who had had a stroke and found that they had a lower quality of life and higher disability compared to the healthy population. A longitudinal cohort study with 803 people with coronary heart disease (CHD) found that people who had depression and anxiety at baseline had a lower quality of life compared to those who had no depression and anxiety at baseline over a three year follow-up (Palacios, Khondoker, Achilla, Tylee & Hotopf, 2016). These findings are consistent with a systematic review of 11 studies that concluded that depression is associated with poor physical quality of life for people with coronary heart disease (Dickens, Cherrington & McGowan, 2012).

Health-related quality of life is considered to be an important indicator of the effectiveness of any treatment in people with heart disorders (Garster, Palta, Sweitzer,

Kaplan & Fryback, 2009). There are two kinds of quality of life measures. The first pertains to generic measures, such as the World Health Organization Quality of Life measure WHOQOL (WHO, 1998) and the 36- item Short-Form Health Survey (SF-36) (Hays, Sherbourne & Mazel, 1993; Ware & Sherbourne, 1992), assess different aspects of quality of life and can be used for a wide range of psychological and physical conditions. Second, there are specific disorder quality of life measures that can capture some areas that are affected by a particular disorder. For example, the Seattle Angina Questionnaire (SAQ; Spertus et al., 1995) assesses the quality of life for people with angina.

1.2.4.4 CVDs risk factors. Notably, depression has been associated with some CVD risk factors, including unhealthy behaviours, like smoking or drinking (Khawaja et al., 2009), physical inactivity (Bonnet et al., 2005; Naylor et al., 2012; Win et al., 2011) and poor diet. It also leads to greater inability to perform routine activities for heart disease people (Walters, Barley, Mann & Phillips, 2014). Depression also has been correlated negatively with people self-care and self-efficacy (Cameron, Worrall-Carter, Riegel, Lo & Stewart, 2009; Holzapfel et al., 2009).

Other mental health problems, such as anxiety and irritability after myocardial infarction (MI), have been associated with speeds of recovery, ability to adjust to medical problems (Melamed, Heruti, Shiloh, Zeidan & David, 1999), quality of life and increased functional disability (Yohannes, Willgoss, Baldwin & Connolly, 2010). Anxiety has also been related to worse major adverse cardiac events, such as heart attacks and cardiac death (Frasure-Smith & Lesperance, 2008). Stress has also been found to be associated with myocardial ischemia (Gullette et al., 1997; Strike & Steptoe, 2003).

An important point regarding the literature of comorbidity between depression/other mental health problems and CVDs is that most of studies examining mortality rate, worse outcomes and the risk factors of CVDs used association designs, thus it was not possible to establish good evidence around causality. To summarise, depression and cardiovascular disorders (CVDs) have a notable prevalence within the UK, being associated with poor medication adherence and medical outcomes, low quality of life and increased use of the health service. However, there were methodological limitations in studies examining the comorbidity between depression and CVDs, including study design, use of depression self-reported measures, measuring depression at baseline only, the heterogeneity of heart conditions and follow-up length. It is important to determine the underlying links (mechanisms) between depression and CVDs in order to identify and develop new treatments that can target such mechanisms. The next subsection reviews some of mechanisms of the relationship between depression and CVDs.

1.2.5 Underlying links between depression and CVDs.

Evidence shows that there is a combination of biological, environmental, psychological and social factors that may explain why depression is linked to CVDs (Naylor et al., 2012), including, cigarette smoking, hypertension, diabetes, obesity, poor nutrition, sedentary lifestyle, stress, reduced functional capacity, nonadherence to cardiac prevention, lower heart rate variability (HRV), lack of physical activity, poor self-care and inflammation (Cameron et al., 2009; Carney, Freedland, Miller & Jaffe, 2002; Dickens, 2015; Guarneri, Mercado & Suhar, 2009; Miller & Blackwell, 2006).

Theoretically, some models have been proposed to explain the relationship between depression and CVDs. For example, Lett and colleagues (2004) suggested a model for biobehavioural mechanisms with two interacting factors that explain why

depression causes subsequent cardiac events. The first pathway includes behavioural risk factors, such as smoking, physical activity and medical adherence, whilst the second includes physiological risk factors, such as inflammation, platelet activity, diabetes, hypertension and obesity. Consistent with this biobehavioural model, Huffman and colleagues (2013) proposed a model that includes two factors (impaired health-promoting behaviour and adverse physiologic effects). In this model, depression in people with cardiac problems leads to impaired health-promoting behaviours that consequently, results in reduced adherence to a low-fat diet, physical activity, medication and rehabilitation attendance. At the same time, depression causes adverse physiologic effects that lead to, for example, increased inflammation and decreased heart rate variability. Taken together, these factors can cause adverse cardiac events. Empirically, numerous studies have explored various biological, behavioural, social and psychological mechanisms linking depression to CVDs. The evidence for some of these mechanisms is described below, with a particular focus on possible psychological factors.

1.2.5.1 Some biological and behavioural mechanisms.

One possible biological mechanism is platelet reactivity. Laghrissi-Thode, Wagner, Pollock, Johnson & Finkel (1997) found that people with depression compared to people without in ischemic heart disease population showed higher reactivity of platelet aggregation (the process by which cells form clots in the blood stream), which is known to trigger heart attacks, strokes, and peripheral vascular disease (Gregg & Goldschmidt-Clermont, 2003). Serebruany et al. (2003) concurred with Laghrissi-Thode et al. (1997) that people with depression and acute coronary syndrome (ACS) were likely to have a higher platelet reactivity than a healthy group.

Another possible biological mechanism that has recently received increased attention is inflammation, which is defined as “a primary component of the immune system that is triggered by any stimulus that poses a real or perceived threat to tissue homeostasis” (Maskrey, Megson, Whitfield & Rossi, 2011, p. 1001). Stewart, Rand, Muldoon & Kamarck (2009) conducted a study over six years to examine whether baseline depression, as assessed by the Beck depression inventory (BDI), would predict inflammation markers (interleukin-6 (IL-6) and C-reactive protein (CRP) in healthy people ($n = 263$). The authors found that people with high baseline depression showed higher levels of interleukin-6 (IL-6) compared to those with less baseline depression. Poole, Dickens & Steptoe. (2011) concluded that, in a sample of people with acute coronary syndrome (ACS) and coronary artery bypass graft (CABG), inflammation is associated with the onset of depression and adverse cardiac outcomes.

There is also increasing evidence that behavioural mechanisms, including non-adherence to medication and unhealthy behaviours (e.g., cigarette smoking and physical inactivity) may have a negative impact on cardiac outcomes. Gehi, Haas, Pipkin & Whooley (2005) found in a sample of people with coronary heart diseases ($n = 940$) that people with current major depression reported less adherence to medication compared to those without it. These findings were elicited after controlling for cardiac disease severity, age, ethnicity, education and social support. Rieckmann et al. (2006) agreed with Gehi et al.'s (2005) study outcomes, eliciting that people with coronary artery syndrome (CAS) who had high baseline depression during hospitalisation were likely to report less adherence to medical medication over 3-months follow up compared to those without depression. A clinical review of the relationship between depression and CVDs concluded that people with depression

reported a twofold non-adherence rate to medication (cardiac or psychiatric) compared to people without it (Hare, Toukhsati, Johansson & Jaarsma, 2014).

Bonnet et al. (2005) studied unhealthy behaviours in people ($n = 1,612$) at high risk of CVDs and concluded that unhealthy diet, cigarette smoking and physical inactivity were associated with depression and anxiety. Whooley et al. (2008) followed people with coronary heart disease (CHD) over six years and found that physical inactivity played a role in relation to the association between baseline depression and an adverse cardiac event. Also, depression and physical inactivity, together, were found to be associated with a higher mortality rate compared to people with one of these manifestations alone (Win et al., 2011).

In conclusion, despite the long history of examining the potential role that biological/behavioural factors may play in how depression is linked to CVDs, it would still seem that much of this relationship has yet to be explained. Recently, the interest has been directed towards psychological factors, including self-efficacy and related self-care as well as psychological resilience, rumination and worry, all of which have been identified as important factors that need to be targeted, the evidence regarding each of these is presented below.

1.2.5.2 Psychological mechanisms.

1.2.5.2.1 Rumination and worry. Perseverative/repetitive negative thinking is defined as “a style of thinking about one’s problems (current, past, or future) or negative experiences (past or anticipated) that shows three key characteristics: (1a) the thinking is repetitive, (1b) it is at least partly intrusive, and (1c) it is difficult to disengage from” (Ehring et al., 2011, p. 226). According to Ehring & Watkins (2008), there are three characteristics associated with repetitive negative thinking: passivity or uncontrollability, negativity and repetition. The main perseverative negative cognitive

processes include rumination and worry. Nolen-Hoeksema (1991) describes rumination as a “a mode of responding to distress that involves repetitively and passively focusing on symptoms of distress and on the possible causes and consequences of these symptoms” (p. 1). Some studies have suggested that rumination has two types (brooding and reflection), with the former being a passive focus on distress symptoms and the latter an active attempt to understand the problem (Sorg, Vögele, Furka, & Meyer, 2012). With regards to worry, it refers to “a chain of thoughts and images that are affectively negative and relatively uncontrollable” (Borkovec, Robinson, Pruzinsky & DePree, 1983, p. 10).

Importantly, Harvey, Watkins, Mansell, & Shafran (2004) suggest that perseverative negative thinking is a transdiagnostic process as it presents with a large number of disorders. Despite rumination and worry being intrinsically linked, there is a notable difference between the two, with rumination focusing on the past and worry on the future (Ehring & Watkins, 2008). Practically, rumination has been shown to increase the likelihood, severity and duration of depression (Watkins, 2008; Watkins & Teasdale, 2004) as well as predict the onset and recurrence of depressive episodes (Sorg et al., 2012). Also, it has been found that brooding as a type of rumination is related to concurrent and prospective depression (Ehring & Watkins, 2008).

Brosschot, Gerin, & Thayer (2006) explain how these perseverative cognitive processes are related to physical conditions in their perseverative cognition theory. Under this theory, perseverative cognition is described as “the repeated or chronic activation of the cognitive representation of one or more psychological stressors” (Brosschot et al., 2006, p. 114). The authors suggest that a perseverative cognition can last way beyond the duration of the stressor. Ill health can be induced by expanding the temporal duration of the stressor beyond its natural reaction period by including

recovery and anticipation, thereby prolonging the physiological activation. Gerin et al. (2012) and based on this theory, propose a model that describes rumination as a mediator of chronic stress effects on hypertension. They suggest that rumination around a stressful event can cause activation of a physiological response similar to that happening during the original stressful event, which can continue for a long time after its conclusion and thus, leads to high blood pressure.

A number of authors have associated the perseverative cognitive processes with CVDs, including hypertension and coronary heart disease (Gerin et al., 2012; Kubzansky et al., 1997; Radstaak, Geurts, Brosschot, Cillessen, & Kompier, 2011). Trick, Watkins, Windeatt, & Dickens (2016) completed a systematic review that focused on the temporal relationship between depression, anxiety and emotional distress and perseverative negative thinking. The uncontrolled studies included in the review showed that there was an association between catastrophising and rumination with depression, anxiety and emotional distress. While, the studies that controlled for covariates, such as baseline depression, reported mixed outcomes. Also, the review showed that the controlled studies did find that catastrophising resulted in the strongest associations. Importantly, this review showed that people with chronic pain and cardiovascular disease have a greater association between perseverative negative thinking and anxiety, emotional distress and depression.

Moulds et al. (2008) discuss some similarities between rumination and cognitive reactivity which refers to “the degree to which a mild dysphoric state reactivates negative thinking patterns” (Raes, Dewulf, Van Heeringen, & Williams, 2009, p. 623). For example, both concepts describe an individual’s response to low mood and can be used as a vulnerability factor to predict depression recurrence (Moulds et al., 2008). Moulds et al. (2008) in their study, showed that there was a

positive correlation between rumination and cognitive reactivity even after controlling for the current level of depression.

1.2.5.2.2 Self-efficacy and related variables. The concept of self-efficacy was first introduced by Bandura (1977) in his theory of personal expectations and their impacts on health outcomes. It can be defined as “people’s confidence in their ability to take care of their health” (Sarkar, Ali & Whooley, 2007, p. 2). Accordingly, applying this notion to CVD populations, the more confidence that a person with cardiac problems has in terms of controlling their condition the greater the likelihood of positive cardiac outcomes.

Practically, self-efficacy was found to be associated positively with motivation and performance in learning settings (Vancouver & Kendall, 2006) and health behaviour changes (Strecher, McEvoy DeVellis, Becker, & Rosenstock, 1986). Also, self-efficacy has been found to be a mediator⁶ of the relationship between depression and CVDs (Greco et al., 2014). In addition, it has been revealed that low self-efficacy predicts lower quality of life for people with depression (Loo et al., 2016) and mediates the relationship between depression and adherence (Tovar et al., 2015). Also, low self-efficacy is associated with high symptoms burden, physical limitations in people with chronic heart failure (Sarkar et al., 2007) and post-stroke depression (PSD) (Volz, Mobus, Letsch & Werheid, 2016).

Interestingly, Sarkar, Ali, & Whooley (2009) found in a sample of people with heart failure (HF) that low self-efficacy was able to predict all-cause mortality and a greater hospitalisation rate for HF reasons. However, the findings of this study may have been limited by methodological issues. For example, the authors discussed the

⁶ A mediator is defined as “an intervening variable that may account statistically for the relationship between the independent variable and dependent variable” (Kazdin, 2007, p. 3).

issues around measuring self-efficacy at baseline only, which means that there are likely to be other important factors that appear on a longitudinal basis. Also, there is an issue regarding the used self-efficacy measure, in that it was only a 5-item self-report. A systematic review of management programmes in people with CVDs has suggested that interventions would benefit from including self-efficacy as a component (Katch & Mead, 2010).

Self-care, which is related to self-efficacy, is another issue that has been noticed as affecting medical outcomes and family function in people with chronic heart failure (Riegel, Dickson, Goldberg & Deatruck, 2007). A study (Holzapfel et al., 2009) pertaining to people with chronic heart failure measured self-care in three groups, people with: major depression, minor depression and non-depressed people. The findings indicated that those with minor depression reported lower self-care compared to the other two groups. The authors attributed this counter-intuitive finding to people with serious conditions, including major depression, focusing more on self-care compared to those with only minor symptoms, as their awareness of the need to take care of themselves is more acute and pervasive. However, we think that it is more likely that the findings were the result of methodological limitations, such as the stage of heart failure, the sample size and the depression assessment method. Additionally, it has been shown that people with good self-care are likely to have better health improvement, less inflammation and less hospitalisation than those without it (Riegel, Lee & Dickson, 2011). The ways of taking care of a CVD condition differ depending on the type of CVD and its severity, with some of these including keeping to a diet, undertaking physical activity, attending rehabilitation programmes and taking medication, either psychiatric or medical.

Psychological resilience is another factor that has been found to be related to some physical conditions, including cardiovascular disorders and refers to “people’s ability to “bounce back” from stressful experiences quickly and efficiently” (Carver, 1998, p. 246). A main difference between self-efficacy and resilience is that resilience presents if there is a stressful event while self-efficacy can be present regardless of stressful events (Schwarzer, R., & Warner, 2013). A study (Schure, Odden, & Goins, 2013) with old people found that resilience was negatively associated with depression. Also, resilience has been found to affect the relationship between depression and psychological quality of life in people with heart failure (HF) (Liu, Chang, Wu, & Tsai, 2015). Toukhsati, Jovanovic, Dehghani, Tran & Tran (2016) conducted a study with people with CVDs and found that low psychological resilience is significantly associated with depressive symptoms; mainly anhedonia and hopelessness.

1.2.5.2.3 Illness perception. Symptom and illness perception is a variable found to be associated with people’s perceptions of their health. It refers to “the process of becoming aware of bodily dysfunction” (Van den Bergh, Bogaerts, & Diest, 2015, p. 866). This concept assumes that the physical symptoms that people experience and describe are an interpretation of their inherent beliefs regarding interoceptive information. That is, they are descriptions based more on symptom perception that developed from previous learning of the potential causes of somatosensory inputs than on direct records of physical activity within their body (Van den Bergh et al., 2015). In their recent model, Van den Bergh, Witthoft, Petersen, & Brown (2017) proposed that experience of somatic symptoms is as a result of ongoing interplay between ‘priors’ and ‘prediction errors’. Symptom perception is potentially influenced by a range of factors, including symptom schemata, threat, negative affect (NA), illness beliefs, anticipation, varieties of attention and gender (Van den Bergh et al., 2015). One of

these factors, namely symptom schemata, comprises representations of an individual's history of symptom episodes that have been stored in their memory and includes aspects that are common to episodes experienced by that individual (Van den Bergh et al., 2015). With regards to negative affect (NA), it has been found that trait NA, affective disturbance and anxiety states are associated with an increase in reporting of physical symptoms (Van den Bergh et al., 2015). Hagger & Orbell (2003) reported that the concepts of coping mechanisms, perceptions of risk and psychological well-being are related to individuals' thoughts and concerns about specific aspects that might constitute their cognitive models of their illnesses. Such a model may include the condition nature and its causes, timeline and consequences and the potential for its control (Hagger & Orbell, 2003).

The self-regulation model (SRM), as described by Leventhal, Diefenbach, & Leventhal (1992), is one of the most prevalent theoretical frameworks applied to cognitions associated with health and illness. In this model, individuals are regarded as building personal representations, which subsequently have an impact on making sense of their experiences. The SRM proposes that an individual's illness perceptions are organised around the following components: identity (the tag, or label a person employs to provide an account of their illness, along with the symptoms that are perceived as part of the condition); timeline (a person's perception of the length of time for which they will suffer from the condition); control (whether the illness can be controlled); consequences (how severe the impacts of the condition in terms of its physical, psychological, and social implications); cause (reasons for the condition); and coherence (whether the condition is comprehensible) (Petrie, Weinman, Sharpe, & Buckley, 1996).

Practically, examining of the way in which these illness perceptions impact on health and health-related outcomes has been studied in the literature. This is especially with respect to cardiovascular disorders (CVDs) and certain psychological problems, including depression and anxiety. It has been shown that illness perceptions are related to some important outcomes, including adjustment, self-reported well-being and functional status, survival and return to work in people with heart diseases (Barefoot et al., 2011; Petrie, Weinman, Sharpe, & Buckley, 1996). Moreover, evidence indicates that illness perceptions are related to seeking- help in people with different physical conditions (Hsiao, Chang, & Chen, 2012; Morgan, Villiers-Tuthill, Barker, & Mcgee, 2014). For instance, if people believe that their conditions are serious, then they are more likely to seek help (Hsiao et al., 2012). Also, a study conducted by Hallas, Wray, Andreou, & Banner (2011) found that negative illness perceptions (particularly relating to heart failure consequences) contributed to an increased likelihood of inappropriate coping strategies (e.g., denial and introversion). van der Wal, Stromberg, van Veldhuisen, & Jaarsma (2016) showed that people with heart failure (HF) who have negative expectations such as “my condition is going to be worse” are likely to have worse outcomes.

Adherence is a crucial factor that has been found to be related to positive physical and psychological outcomes. The degree to which an individual is likely to adhere to any given treatment has been elicited as being correlated with the nature of their beliefs (Hsiao et al., 2012; Petrie et al., 1996). Petrie et al. (1996) found that people’s initial beliefs about myocardial infarction (MI) were associated with adherence-related variables, including presence at cardiac rehabilitation sessions and return to work. Also, there is evidence that indicates that people’s medication-related beliefs are correlated with adherence. In fact, Horne & Weinman (1999) found that

people beliefs about their illness had greater predictive power in determining adherence when compared to clinical and sociodemographic characteristics.

It is important to consider how depression may impact on illness related beliefs about CVDs. Given that depression is proposed to lead to global negative beliefs about the self, world and future (e.g., Beck, 1979), it seems likely it would also lead to more negative views about recovery from heart disease. Moreover, given that depression has been associated with elevated rumination (repetitive negative thinking) (see Watkins, 2008), it is likely that individuals with depression will spend more time dwelling on their views regarding, causes, meanings and consequences of recovery from CVDs. These negative and repetitive negative thought cycles may then impact on illness related behaviours, for example reduced adherence to treatment. It is also possible that the relationship could go in the reverse direction. For example, those who hold negative views about recovery from CVD that they dwell on which may in turn become more depressed. These ideas have only partially been tested in the literature, which has established illness beliefs around CVDs and depression are related but have not established the direction or causal nature of these relationships. Researchers have found that emotional outcomes can be predicted by rumination, which in turn, is related to perceived identity, the emotional representation of the illness, the consequences of the illness, and negative emotions (Lu et al., 2014). Morgan, Villiers-tuthill, Barker & Mcgee. (2014) conducted a study on 95 people with heart failure (HF) and found that negative illness perceptions were associated with more marked depression and anxiety. Their study also showed that people with heart failure experienced high negative illness perceptions in some respects, such as their perceived personal consequences of HF and negative emotional responses.

1.3 Depression in the Context of CVDs

Ormel & De Jonge (2011) have proposed an integrative dynamic model aimed at understanding depression in the context of coronary artery disease (CAD). It categorises depression into two types: cognitive/affective (e.g., depressed mood, suicidal thoughts, negative feelings, self-sense of failure, self-criticism, feeling of guilt and/or future pessimism) and somatic/ affective (e.g., fatigability, psychomotor agitation/retardation, work difficulty, sleep problems, pain, appetite disturbance, weight disturbance and/or depressed mood). With this model, the effects of depression on people with CAD are considered to be related not only to these two types, but also, to the longer duration of depression. In addition, notably, this model highlights that behavioural factors significantly impact on the relationship between recurrent depression and cardiac prognosis regardless of the type of depression.

Dickens (2015) conducted a review of depression in people with coronary heart disease (CHD). In this review, Dickens revealed a number of characteristics that could explain why depression leads to worse outcomes in CHD populations, which include: timing of the depression onset, severity of the symptoms and type of depression (somatic or cognitive). The author proposed that this focus on characteristics could be the key to identifying the type of depression and its mechanisms that cause worse outcomes. In addition, this research focus could help in the identification of those people at higher risk of poor outcomes and in the development of novel interventions for reducing the impact of depression on people with CHD. The next subsections consider some of these characteristics.

1.3.1 Types of depression.

The most common type of depressive disorder, which has received much attention in populations with CVD, is major depressive disorder (MDD), whilst minor depression and dysthymia have received less attention in this context. These three types of depression place a significant burden on people with pure or comorbid depression in the context of physical health conditions and have also been related to increasing likelihood of subsequent relapse (Boland & Keller, 2002; Hardeveld et al., 2010; Judd, 1997). Evidence suggests that MDD and dysthymia are associated with poorer comorbid medical outcomes, lower adherence to medication, poor diet, and lack of exercise when compared to people without these conditions in acute myocardial infarction (MI) populations (Kennedy & Foy, 2005; Ziegelstein et al., 2000).

1.3.2 Timing of depression.

There has been some focus in the literature on the timing of depression onset in CVDs (i.e. whether depression is a new event following the cardiac event or there is a history of depression prior to this). This timing of depression onset has been linked to the development or progression of cardiovascular conditions. For example, regarding new-onset depression, a study of 489 people admitted to hospital for acute coronary syndrome (ACS) involved interviewing at one and 12 months to assess for depression. The findings found that after the adjustment of important covariates, people diagnosed with new depression after ACS showed poorer cardiac outcomes compared to those who had a history of depression before it happened (Parker et al., 2008).

However, in a recent UK cohort study (Daskalopoulou et al., 2016) of 1,937,360 adults without cardiovascular disorders at baseline, researchers found that after two to 10 years of follow-up, both a history of and new-onset depression were associated with an increased prevalence in several CVDs, including stable angina,

unstable angina, heart failure, myocardial infarction, cardiac arrest, transient ischemic attack, ischemic stroke and peripheral arterial disease, when compared to those without depression. Also, a systematic review of 17 prospective studies indicated that people with a history of depression had a 34 % higher risk of having a stroke than those without after controlling for certain variables, including age, gender, history cardiac disease history, smoking, hypertension and diabetes. The review also found that depression increases, independently, the risk factors of a stroke, such as hypertension and diabetes (Dong, Zhang, Tong & Qin, 2012). Despite the conflicting evidence around the timing of the onset of depression and its role in worsening cardiovascular outcomes, a meta-analysis by Leung et al. (2012) has highlighted that both (new onset or a history of depression) are important and that the timing is irrelevant when considering adverse cardiac outcomes.

1.3.3 Types of depressive symptoms.

Within the CVD literature, an appreciable amount of attention has been placed on the way depression presents. It is generally agreed that depression can be categorised in a number of ways, including: psychological, cognitive and somatic. There is evidence that different characteristics have different impacts on cardiac outcomes. Regarding which, Smolderen et al. (2009) found a link between somatic depression and elevated rates of myocardial infarction (MI) hospital readmission (Hazard ratio, HR=1.16; 95 % *CI*: 1.06-1.27; $p = 0.01$) that was not presented in cognitive depressive symptoms. These findings are supported in a study by (Martens, Hoen, Mittelhaeuser, de Jonge, & Denollet, 2010), who examined the association between different types of depressive symptoms regarding the severity and prognosis of myocardial infarction (MI). The authors found that somatic depressive symptoms were

associated with returning MI and cardiac mortality, whilst cognitive symptoms had no such association.

Despite the differences in these studies, with regards to depression measures and cardiac risk factors, they have highlighted the importance of the link between CVDs and somatic depression, thus promoting the need for the development of screening and new treatments for people with CVD who show its symptoms.

1.3.4 Recurrent depression and CVDs.

There is evidence that suggests a link between recurrent depression and subsequent cardiac events in people with cardiac diseases. Indeed, a study by Lesperance, Frasere-smith, & Talajic (1996) suggested that recurrent depression is a more important risk factor for CVDs than that of incident depression. The authors reported that people with a history of major depression disorder (MDD), who had a recurrent episode within a week of suffering a myocardial infarction, had a higher incidence of death than those with first time incident depression (40 % compared to 10 %, respectively). A prospective study on 336 healthy women, carried out by Jones, Bromberger, Sutton-tyrrell, & Matthews (2003) determined the associations between subclinical atherosclerosis and recurrent depression. The study showed that a lifetime history of depression was correlated with subclinical atherosclerosis, while there were no associations with single major depressive episodes. A longitudinal study, completed by Windle & Windle (2013), reported a five-year follow-up of 557 people. The study aimed to determine the concurrent and prospective correlations between single and recurrent MDD and diabetes, cardiovascular disease and other CVD risk markers, such as high cholesterol and hypertension. The prospective, cross-sectional analysis showed recurrent MDD was a significant predictor of diabetes and CVD risk and also, an

increase in the risk of both disorders, even after controlling for BMI, smoking and alcohol use, while single episode MDD had no such correlations.

Nevertheless, a number of other studies, including those by Grace et al. (2005), de Jonge et al. (2006) and Goodman et al. (2008) reported that there was a correlation between incident depression at the time of hospitalisation with mortality and future cardiac events, whilst a history of depression showed no such correlations. Carney & Freedland (2012) hold that recurrent depression enhances the development of CVDs by placing people in the risk factor situation for a long time.

It is important to consider the underlying mechanisms through which recurrent depression might be linked to worse cardiovascular disorder prognosis. A range of possible underlying mechanisms has been proposed in the literature (see review by Dickens, 2015). Different lifestyle behaviours associated with depression may lead to poor cardiac outcomes, including: a greater tendency to smoke and a reduced likelihood of discontinuing smoking in depression (Whooley et al., 2008; Ye et al., 2013); a poor diet leading to a greater chance of obesity (especially vascular obesity) and type II diabetes in depression (Knol et al., 2006; Luppino et al., 2010); reduced exercise and a greater likelihood of a sedentary lifestyle in depression (Bonnet et al., 2005; Brummett et al., 2003); reduced adherence to treatment recommendations, both for depression and cardiovascular disorders (Rieckmann et al., 2006, 2011); and poor attendance at cardiac rehabilitation in depression (Casey, Hughes, Waechter, Josephson, & Rosneck, 2008).

Underpinning this poor self-care are likely to be deficits in motivation, reduced sense of self-efficacy, and pessimistic beliefs relating to the potential benefits of treatment (Wang et al., 2002). For instance, self-efficacy has been found to be a mediator of the relationship between depression and CVDs (Greco et al., 2014) as well as mediating the relationship between depression and adherence (Tovar et al., 2015).

Also, low self-efficacy is associated with high symptoms burden, physical limitations in people with chronic heart failure (Sarkar et al., 2007) and post-stroke depression (PSD) (Volz et al., 2016). It has been elicited that self-care, which is related to self-efficacy, influences medical outcomes and family function in people with chronic heart failure (Riegel et al., 2007). Also, it has been shown that people with good self-care are likely to have better health improvement, less inflammation and less hospitalisation than those without it (Riegel et al., 2011).

It is also important to consider the impact that perseverative cognitive processes have on depression and CVDs. Brosschot et al. (2006) explain how these perseverative cognitive processes are related to physical conditions in their perseverative cognition theory. The authors suggest that a perseverative cognition can last way beyond the duration of the stressor (Brosschot et al., 2006). Based on this theory, it is possible to aggravate adverse health conditions, such as CVDs, by augmenting the stressor's timeline far past the natural reaction period, and this can be achieved by incorporating recovery and anticipation, thereby prolonging associated physiological activation (Brosschot et al., 2006). Based on this scenario, an individual may experience elevated blood pressure (BP) long after exposure to a stressor, because of rumination (which, in turn, stimulates a physiological response) (Gerin et al., 2012). The literature suggests that these perseverative cognitive processes are linked with CVDs (e.g., hypertension and coronary heart disease) (Gerin et al., 2012; Kubzansky et al., 1997; Radstaak et al., 2011) and can promote negative prognoses such as impaired immune response (Brosschot et al., 2006). Larsen & Christenfeld (2009) concluded that rumination is a mechanism that links the co-occurrence of cardiovascular disorders and psychiatric disorders. Specifically, the researchers argued that rumination postpones recovery following exposure to stress, which is thus considered a predictor of future

cardiovascular health (Larsen & Christenfeld, 2009). Busch, Pössel, & Valentine (2017) meta-analysis, which investigated rumination as a potential causal explanation for the link between depression and CVDs, revealed that rumination (irrespective of its types) stimulates significant cardiovascular reactivity. Trick et al. (2016) concluded that there is a connection between perseverative negative thinking and emotional distress, depression, and anxiety in people with CVD and chronic pain. Regarding depression populations, Sorg et al. (2012), Watkins (2008), and Watkins & Teasdale (2004) have found that rumination is linked to an increased likelihood of initial and recurrent depression, along with more severe and longer depressive episodes.

It is also possible that the increased and chronic inflammatory response seen in depression may worsen cardiovascular disorders (Dickens, 2015). Research indicates that elevated inflammation and inflammatory cytokine levels constitute risk factors for coronary disease. In particular, they have an adverse impact on the pathogenesis of coronary heart disease (Berton et al., 2010; Poole, Dickens, & Steptoe, 2011). Furthermore, the literature suggests that depression is associated with a heightened level of various inflammation biomarkers, including c-reactive protein (CRP), interleukin 1 (IL-1), and interleukin 6 (IL-6) (Howren, Lamkin, & Suls, 2009; Stewart et al., 2009).

The social signal transduction theory of depression (Slavich & Irwin, 2014), which connects stress to internal biological mechanisms (primarily inflammation) associated with the development of depression suggests ways in which experiential stress impacts on inflammation, along with the ways stress-inflammation pathways may be related to depression. The authors hold that sympathetic nervous system (SNS) and hypothalamic–pituitary–adrenal (HPA) responses to stress are potentiated by past experiences with depression, thereby facilitating the galvanisation of the regulatory

connection between the brain and the body's inflammation system. Based on this theory, the two-way connections between the brain and inflammatory system become stronger over time and the neural and physiological pathways responsible for regulating inflammation could stay active without being exposed to stress (Slavich & Irwin, 2014). This chronic inflammation may exacerbate CVD risk.

Finally, it is important to mention that most of the existing literature has focused on studying the links underlying the relationship between CVDs and single episode depression. Further work is needed to examine whether recurrent depression further exacerbates this picture.

1.3.5 Depression in elderly people with CVDs.

Importantly, given that high numbers of people with CVD are elderly, it is important to note that depression in this context can come with different symptoms. More prevalent in this age group are loss of enjoyment, increased lack of energy and somatic symptoms, whilst less prevalent are sadness or a depressed mood (Wilson, Mottram & Vassilas, 2008). Also, there is an overlap between depression and some symptoms of CVD, which can lead to difficulty in making a differential diagnosis. For example, symptoms such as weight change, fatigue and insomnia in congestive heart failure can be misdiagnosed as depression (Rustad et al., 2013).

In summary, the previously mentioned published studies have provided evidence showing that depression is linked to poor cardiac outcomes with regards to quality of life, medication adherence and rehabilitation. Whilst considerable attention has been focused on people with CVD with major depression, there has been a lack of studies that have considered minor depression or dysthymia. Nonetheless, whilst it is acknowledged that depression or mental health problems are burdensome for all affected, people with CVD are faced with considerable struggles due to low self-

efficacy, poor quality of life, poor illness perception and decreased self-care.

Consequently, it is important to consider these factors in any interventions for people with depression and CVD. The existing treatments for depression in the context of CVDs are described below.

1.4 Existing Treatments for Depression in the Context of CVD

As mentioned previously, depression is an important risk factor for developing and/or progressing a wide range of cardiovascular disorders, having a significant impact on all aspects of a person's life, including increasing healthcare costs. Consequently, treating comorbid depression in such populations with these disorders is essential for improving CVD outcomes. The National Institute for Health and Care Excellence (NICE) has proposed that treating depression in people with chronic physical health problems is likely to increase the quality of life and life expectancy (NICE, 2009). At present, there are different psychiatric, psychological and behavioural treatments that can help people with CVDs (Lichtman et al., 2008). Some of these are targeted at decreasing comorbid mental health problems, such as depression and anxiety, whilst others are focused on the risk factors relating to CVDs, such as a high blood pressure and physical inactivity.

One of the key treatments for depression in the context of CVD is antidepressant medication. Some research was conducted to target the biological mechanisms linking depression and CVDs, such as platelet activity and inflammation. Regarding which, Serebruany et al. (2003) showed that the selective serotonin reuptake inhibitor sertraline (SSRIs) when compared to a placebo led to platelet activation reductions. Other research was aimed at investigating the effectiveness of antidepressants on cardiovascular mortality and morbidity. For example, Kimmel et al. (2011) found that prolonged use of selective serotonin reuptake-inhibiting

antidepressants (SSRIs) led to a reduction in the risk of myocardial infarction (MI) (odds ratio = 0.77, 95 %, *CI*: 0.57, 1.03) in a group of people with depression compared to those without. Also, there is evidence that using antidepressant medications decreases comorbid mental health problems, including MDD, anxiety and stress in people with CVDs (Lichtman et al., 2008; Thombs et al., 2008).

However, antidepressants have been found to be related to an increase in stroke risk and myocardial infarction (Smoller et al., 2009; Undela, Parthasarathi, & John, 2015) as well as adverse cardiac events (Ramamurthy, Trejo, & Faraone, 2013). Approximately 90 % of 943 people treated with citalopram reported at least one residual symptom, with sleep disturbance being the most common persistent symptom (Nierenberg et al., 2016). It has also been found that physical burden can affect the response to antidepressants (Habra et al., 2010). In addition, people's choice is important for consideration, as some are averse to taking medication.

Consequently, recent treatment guidance for depression in people with long term conditions has recommended using conventional psychological treatments alongside antidepressants, including cognitive behavioural therapy (CBT) and interpersonal therapy (NICE, 2009). In a big randomised controlled trial (Berkman et al., 2003), people with post myocardial infarction ($n = 2481$) and major depressive disorder or minor depression were randomised to CBT or TAU plus education. The findings showed that the CBT group showed better improvements in depression compared to the TAU group at 6 months follow up, however, the latter showed improvements as well. Another randomised controlled trial, targeting people who had major or minor depression after coronary artery bypass surgery using CBT, found that CBT showed large effect sizes compared to supportive stress management and usual care (Freedland et al., 2009).

According to Dickens et al., 2004, recurring physical symptoms, greater anxiety regarding wellbeing and persistent social problems may decrease the response to these psychological treatments. Furthermore, conventional psychological treatments can put substantial demands on people in relation to remembering past difficult experiences, challenging maladaptive thoughts and changing their behaviour. For people suffering from cardiovascular disorders, especially those who have suffered a recent serious threat to their life following a stroke or heart attack, this may be burdensome. Hence, researchers should consider when a psychological treatment is offered. For instance, it may not be appropriate to offer therapy immediately post a cardiac event. Additionally, treatment must be cost-effective and as a result, group treatment may be preferable to individual therapy.

Consequently, there is a need for a psychological intervention that leads to behaviour change (Casey, Hughes, Waechter, Josephson & Rosneck, 2008) and helps people to make a full recovery from depression by targeting residual depressive symptoms (Boulenger, 2004; Vos et al., 2004). In addition, there needs to be a focus on staying well over the long-term, given the chronic relapsing nature of depression. Relapse prevention has arguably not received sufficient attention in the CVD literature and mindfulness interventions have the potential for reducing depressive relapse rates as well as dealing with depressive residual symptoms.

1.5 Mindfulness-Based Interventions

Mindfulness is defined as “paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally” (Kabat-Zinn, 1994. p. 4). Initially, mindfulness-based interventions (MBIs) were developed as a type of treatment for pain, low mood and health-related anxiety. These interventions teach people different ways to regulate their feelings, thoughts and body sensations by paying attention to the

present experience with an attitude of allowing curiosity, kindness and patience.

Mindfulness-Based Stress Reduction (MBSR) (Kabat-Zinn, 1990, 2013) is one popular mindfulness programme, during which people are exposed to core mental exercises that focus on breathing and body scanning along with physical exercises that concentrate on bodily sensations.

1.5.1 Mindfulness-Based Cognitive Therapy (MBCT).

Mindfulness-Based Cognitive Therapy (MBCT) was developed by Segal, Teasdale and Williams (2002, 2013) to prevent depressive relapse in people with a history of recurrent major depression disorder (MDD). This course is an 8-week group-based programme, based on MBSR, which cultivates the capacity to ‘attend to’ whatever is happening in ways that are purposeful and well-balanced. MBCT releases the mind from habitual patterns that undermine coping and lead to anxiety and depression (Kuyken et al., 2010), thus facilitating more resilient responses to challenges. It enables perseverative cognitions, such as worry and rumination, to be recognised and responded to in a “decentered” way. MBCT is an integrative therapy that combines meditation exercises and certain cognitive therapy techniques. Such integrative therapies seem to have the potential to fit with different people, problems and contexts as well as to be more flexible in relation to people’s needs (Norcross & Wampold, 2011).

1.5.1.1 MBCT with depression. A substantial body of research has focused on the efficacy⁷ or effectiveness⁸ of MBCT in preventing people with a history of recurrent MDD from relapsing. In early research, Ma & Teasdale (2004) revealed that individuals with more than three episodes showed less depression relapse following

⁷Studies that are conducted to test the effects of an intervention in a research setting.

⁸ Studies that are conducted to test the effects of an intervention in the real world.

MBCT compared to a treatment as usual (TAU) group over 12 months. Similarly, Godfrin & van Heeringen. (2010) found that people with three and more previous episodes in MBCT plus TAU group showed a lower depression relapse rate over 12 months compared to a TAU alone group.

Using antidepressant medication as a comparator, Kuyken et al. (2008) found that an MBCT group did not differ from a maintenance antidepressant medication (m-ADM) group in terms of relapse rate and residual depressive symptoms. However, Segal, Martin & Joseph (2010) reported that MBCT and maintenance antidepressant medication (m-ADM) groups showed a lower relapse rate compared to a placebo group for people with unstable remission. Another RCT (Huijbers et al., 2015) found no differences between MBCT plus maintenance antidepressant (m-ADM) and m-ADM groups in terms of relapse prevention over 15-month follow-up. A recent randomised controlled trial (RCT) (Kuyken et al., 2016) with 424 people with recurrent depression, randomised to MBCT with medication tapering or to maintenance antidepressants (m-ADM) over 24 months of follow-up, revealed that both treatments were effective in terms of relapse rate and residual depressive symptoms, but that there was no difference between them.

An RCT study (Williams et al., 2014) comparing MBCT to cognitive psychological education (CPE) and treatment as usual (TAU) for 274 people with history of MDD (at least three episodes) found no significant differences between the three groups in terms of relapse prevention over 12 months, with MBCT outperforming the other conditions in people with a history of childhood trauma. Piet & Hougaard (2011), in their systematic review and meta-analysis, concluded that MBCT was effective in terms of relapse prevention, especially for people with at least three or more previous MDD episodes. Similarly, another systematic review (Chiesa & Serretti,

2011) found that the effects of MBCT were similar to the antidepressant effects on relapse rates.

Considering residual depressive symptoms, Barnhofer and his colleagues (2009) conducted a pilot RCT assessing the efficacy of MBCT for people with chronic depression. They found that people in the MBCT group showed reductions in residual depressive symptoms compared to a TAU group. Geschwind, Peeters, Huibers, Van Os & Wichers (2012), in their RCT, compared people with two or three previous episodes of depression, finding that MBCT led to decreased residual depressive symptoms regardless of the number of previous episodes, compared to treatment as usual (TAU) group. A recent RCT (Eisendrath et al., 2016) with people with treatment-resistant depression revealed that an MBCT group showed greater reduction in depression severity and better responses to the treatment compared to those undertaking a Health Enhancement Programme (HEP) (a mixture of aerobic exercise, functional movement, music therapy and dietary education). Levels of residual symptoms may moderate the efficacy of MBCT at relapse prevention. A recent individual patient data meta-analysis found that MBCT is more effective for people with high severity of residual symptoms who have had recurrent depression (Kuyken et al., 2016).

There have been a few studies examining effects of MBCT on dysthymia and minor depression and their results were promising. Kenny & Williams (2007) showed a significant improvement in depressive symptoms following MBCT intervention in people suffering from dysthymia, bipolar or MDD. Similarly, another study (Mathew, Whitford, Kenny, & Denson, 2010) of people with MDD, bipolar or dysthymia showed improvements in depressive symptoms post-MBCT treatment. A randomised control comparison study completed by Hamidian, Omid, Mousavinasab, & Naziri (2013),

showed that combining MBCT with antidepressant medication led to better outcomes for people with dysthymia compared to antidepressant medication alone group.

Regarding minor depression, Kaviani, Hatami, & Javaheri (2012) in their study, which focused on people with minor depression, reported improvements in depression, quality of life, anxiety and negative automatic thoughts following the MBCT intervention, when compared to a control group. Similar results were reported by Pots, Meulenbeek, Veehof, & Klungers (2014) from their randomised control trial that compared MBCT intervention with a control group. The participants in MBCT group showed improvements in anxiety, mindfulness, depression, emotional and psychological well-being as well as experiential avoidance. However, despite the positive results that have been reported in these studies with people with dysthymia and minor depression, the methodological issues, such as the design used as well as the depression types, need to be borne in mind.

As there is evidence that MBCT is effective in treating residual depression and reducing relapse rates, whether it could be useful in the context of physical health conditions, including CVDs, is considered next.

1.5.1.2 MBCT with physical conditions. The literature about the efficacy of MBCT with physical conditions is still in its early phase, but there are promising results. For example, MBCT has been shown to have more impact on depression, trait anxiety and dispositional mindfulness for people with inflammatory bowel disease (IBD), when compared to a control group (Schoultz, Atherton & Watson, 2015). A study in individuals with multiple chemical sensitivities (MCS) found that an MBCT group showed better coping strategies and sleep quality compared to a control group, while there were no differences in psychological distress or illness perceptions (Skovbjerg, Hauge, Rasmussen, Winkel & Elberling, 2012). For people with type 1 and

2 diabetes, MBCT has been found to be effective in terms of perceived stress, anxiety and depressive symptoms compared to a TAU group. However, the findings also indicated that there was no difference between the two groups regarding diabetes distress and HbA_{1c} (the amount of glycated hemoglobin in blood) (van Son et al., 2014). Moreover, MBCT has also been used with those with serious physical conditions, such as cancer and has delivered promising findings in relation to chronic cancer fatigue, when compared to a waiting list control group, but exhibited no differences in terms of functional impairment (Van Der Lee & Garssen, 2012). However, whilst MBCT has been designed as prevention programme, it is noted that most of studies targeting physical conditions have not examined its effects on relapse rate or the treatment of residual depressive symptoms.

1.5.1.3 MBCT with CVDs. Conceptually, there are reasons to believe that MBCT may act on key trans-diagnostic mechanisms known to maintain depression and this may also be important in CVDs, especially in relation to rumination and worry. For example, rumination and worry have been found to be associated with developing or progressing depression (McLaughlin & Nolen-Hoeksema, 2011; Watkins, 2008; Watkins & Teasdale, 2004) and has also emerged that subsequent depression episodes can be triggered by ruminative thinking (Nolen-Hoeksema, 1991, 2000). Moreover, rumination would appear to predict relapse in people with MDD (Michalak, Holz, & Teismann, 2011). With regards to CVD populations, rumination and worry have been found to be associated with coronary heart disease and hypertension (Gerin et al., 2012; Kubzansky et al., 1997; Radstaak et al., 2011). Practically, MBCT has been shown to reduce levels of rumination and worry significantly in people suffering from major depression (Kingston, Dooley, Bates, Lawlor & Malone, 2007; Michalak et al., 2011; van Aalderen et al., 2012).

To this researcher's knowledge, only one study (O'Doherty et al., 2015) has been conducted to assess the efficacy of MBCT for people specifically with coronary heart disease (CHD), who suffer from current major depressive disorder (MDD). This study used a controlled design to compare standard-MBCT ($n = 60$) and a waitlist group ($n = 57$) on current depression, quality of life and adjustment to illness. The recruitment process was carried out over approximately three years, with cardiology wards being the main resource for recruitment. The findings indicated that people in the MBCT group showed improvements on current depression, quality of life and adjustment to illness with medium to large effect sizes. Whilst this study was one of the first that used MBCT with heart conditions and current depression, the non-randomised design used was a shortcoming in terms of assessing the efficacy of the treatment and thus, further research is needed. Also, the standard MBCT programme was used rather than making a bespoke adaptation to meet the needs of people with comorbid CVD. Consequently, further research needs to be conducted utilising an improved study design. One such method is a randomised control trial design testing a bespoke adaptation of MBCT to a control condition in terms of its impact on preventing relapse and treating residual symptoms in the context of CVDs.

1.5.2 Methodological issues around mindfulness research.

A notable point, is that mindfulness interventions studies either targeting psychological or physical conditions seem to have experienced limitations in terms of their ability to link research and practice. Dimidjian & Segal (2015), in their review of the mindfulness field, noted a gap between mindfulness interventions research and practice. In response, they proposed a "mapping approach" based on the National Institutes of Health (NIH) stage model (Onken, Carroll, Shoham, Cuthbert, & Riddle, 2014) to assist with the development and improvement of mindfulness interventions.

They also put forward recommendations that might fill the existing gaps between research and practice. Also, Davidson & Kaszniak (2015) reviewed the conceptual and methodological issues surrounding mindfulness research and highlighted a number of improvements that could improve practice. As an example, they emphasised the importance of describing the delivery of the intervention. In addition, they discussed the difficulties associated with assessing mindfulness interventions using randomised controlled trials and suggested the use of an active comparator in dual blind study designs as well as a multi-measure, which would help in the capture of the mindfulness construct.

To summarise, MBCT, as a mind-body intervention, has shown positive effects on depression outcomes in RCTs targeting recurrent depression. Also, it has shown promising outcomes in relation to a wide range of psychological symptoms across diverse physical conditions, but this evidence is still in its early phase. However, mindfulness intervention studies suffer from limitations in relation to linking research with practice.

1.6 Mechanisms of Action

One way to maximise the efficacy of MBCT in a given condition further is to determine its key mechanisms of action (e.g., mediators or moderators) in that sample, and then to refine it so as to focus more on these key mechanisms.

1.6.1 Mechanisms of action in psychotherapy.

For several decades, studying the effectiveness or efficacy of psychotherapies has been one of the main interest of psychological researchers, which has led to a good body evidence on the efficacy of some psychological interventions. However, there has been a lack of explanation as to why or how these interventions produce their effects. Recently, interest in seeing behind the interventions' efficacy through studying the

mechanisms of change has increased. This is because considering these mechanisms might lead to a focus on the salient components of any intervention as well as the identification non-important components that can be removed (Kazdin & Nock, 2003). This should lead to more efficient and streamlined treatments.

Kazdin stated that “beyond knowing that A may cause B, the mechanism elaborates precisely what happens (psychologically, biologically) that explains how B results” (2003, p. 117). Mediators and moderators are two paths for examining mechanisms of change in psychotherapy. Mediators are variables that tell how and why change happens (Johansson & Høglend, 2007), which should correlate significantly with the interventions, come after the intervention and can explain its effects on the outcomes (Murphy, Cooper, Hollon & Fairburn, 2009). Moderators come prior to the intervention, need to be correlated with the intervention and can explain the relationship between the intervention and outcomes as well as help with knowing who would benefit more from the intervention (Johansson & Høglend, 2007; Murphy et al., 2009).

Recently, efforts have been made to establish good practice when studying mechanisms conceptually, such as in the conceptual work of Kazdin (2007, 2009) and the statistical work of Kraemer, Wilson, Fairburn & Agras (2002). Kazdin (2007, 2009) put forward some requirements that need to be considered in order to understand how an intervention leads to a change, including strong association, specificity, consistency, experimental manipulation, timeline and gradient. For example, a timeline criterion refers to the study needing to be able to determine the precedence of the relationship between the mediator and the outcome using multiple assessment time points that can capture the changes over time for both aspects. The Kazdin criteria are explained further in Chapter 2.0. Kraemer and colleagues (2002) have produced a

method by which mechanisms of change (mediators) can be measured statistically in RCTs. In brief, the treatment should affect the outcomes; the mediators should be correlated with the treatment; and the interaction between treatment and mediators should be significant.

1.6.2 Mechanisms of action in mindfulness interventions.

1.6.2.1 Mechanisms of action in MBCT for depression. Recently, there have been some attempts to understand how MBCT works. For example, it has been suggested that changes in mindfulness mediate the efficacy of MBCT on residual depressive symptoms and recurrent depression (Shahar, Britton, Sbarra, Figueredo & Bootzin, 2010; van Aalderen et al., 2012). In addition, rumination, worry and emotional reactivity have been found to have a mediating role on MBCT effects in a recurrent depression population (Batink et al., 2013; Britton, Shahar, Szepsenwol & Jacobs, 2012; van Aalderen et al., 2012). However, in other research rumination seemed not to show up as a mediator for MBCT effects on depression (Bieling et al., 2012; Kearns et al., 2015). According to two recent reviews (Gu, Strauss, Bond & Cavanagh, 2015; van der Velden et al., 2015), the effects of MBCT and MBSR on depression and anxiety are mediated by a range of variables, including mindfulness, rumination, self-compassion and positive affect. However, these two reviews agreed that the extant literature suffers from several shortcomings.

1.6.2.2 Mechanisms of action in MBCT for CVD. As far as this researcher is aware, there has been only one study (O'Doherty et al., 2015) that assessed the mediating role of mindfulness skills in the relationship between MBCT and current depression in people with coronary heart disease (CHD). The findings showed that there are significant associations between increased mindfulness skills and

improvements in outcomes. However, the correlation analysis that was used in this study was not able to test the full mediation of effects of MBCT on depression.

Moreover, the question of how mindfulness interventions might potentially target mechanisms across both physical and psychological health remains largely unanswered. Carlson (2012), in a review, suggested that mindful attention, acceptance and exposure could be common mechanisms across a wide range of physical conditions, including those relating to heart diseases, but these ideas remain largely untested. A recent review by Loucks et al. (2015) identified three mechanisms that may explain the way in which mindfulness interventions can influence the outcomes of CVDs, these being: attention control, emotion regulation and self-awareness. Attention control refers to an individual's ability to keep his/her attention on CVD risk factors, including diet, smoking, physical activity and adherence to medication. Emotion regulation pertains to the way in which the individuals can develop skills to manage cravings for cigarettes, their sedentary lifestyle and poor diet as well as improving their self-efficacy and stress response. Finally, the self-awareness component concerns the physical sensations associated with CVD risk factors and self-referential processing, which is defined as "the cognitive process of relating information, often from the external world, to the self" (Nejad, Fossati, & Lemogne, 2013, p. 7).

1.7 Adapting MBCT for People with CVDs

In addition to the MBCT providing promising results in terms of treating both acute and residual symptoms as well as preventing relapse, there is increased preliminary evidence that it can help to decrease psychological symptoms associated with a number of physical conditions. Also, it has also been shown to be effective in changing other factors, including rumination and worry (Kingston et al., 2007; Michalak et al., 2011; van Aalderen et al., 2012) that have also been linked with CVDs

(Gerin et al., 2012; Kubzansky et al., 1997; Radstaak et al., 2011). Moreover, its group format makes it more likely to be cost-effective than individual interventions.

As standard MBCT is designed solely with a focus on depression and may neglect important parts of the CVD picture, it was surmised by the HeLM team that bespoke adaptations may be required so that it focuses on themes common to both depression and CVDs as well as targeting common underlying mechanisms. In particular, standard MBCT focuses mainly on depression specific mechanisms, for example, rumination about causes, meanings and the consequences of low mood. However, people with cardiovascular disorders worry about the cardiovascular event returning or the causes, meanings and consequences of a cardiac condition (Larsen & Christenfeld, 2009; Rozanski, Blumenthal, & Kaplan, 1999). Moreover, given the nature of cardiovascular disorders, the body cannot be assumed to provide a safe, neutral anchor for mindfulness practice and a different focus may be required; attending to bodily sensations may increase anxiety by activating worries of a further cardiac event, which can increase the pulse and/or heart rate. Furthermore, a number of studies have indicated that people with CVDs have low confidence regarding their ability to take care of their condition, also known as self-efficacy, and the associated impacts on their self-care, which can lead to worse medical outcomes (Greco et al., 2014; Riegel et al., 2011, 2007; Tovar et al., 2015; Volz et al., 2016). Hence, care is needed to consider how best to enhance self-efficacy. This focus would help to maximise the efficacy and acceptability of MBCT for this population.

1.8 Summary of the Literature Gaps and Contributions of the PhD

Cardiovascular disorders are considered to be the main causes of mortality and morbidity in the UK. It is evident that depression is a common and chronic comorbid condition in this population and causes worse medical outcomes and poor adherence to

treatment. MBCT has shown promising effects in terms of decreasing relapse and depressive symptoms in people with recurrent depression. However, in the field of cardiovascular disorders, MBCT has yet to receive sufficient attention in terms of assessing its efficacy. Also, factors such as self-efficacy, self-care, and disorder-specific worries have all been associated with the development and/or persistence of depression and anxiety in those with cardiovascular disorders. Consequently, developing a bespoke MBCT that integrates techniques targeting some of the issues that matter to people with CVDs might improve its efficacy and produce better outcomes. With regards to the mechanisms of action, it remains largely unknown how mindfulness interventions work on physical conditions and hence, future MBCT intervention research needs to involve more systematic evaluation of the mechanisms of action. With awareness of these gaps in the literature pertaining to depression and CVDs, the Heart and Living Mindfully (HeLM) project was conducted to develop and evaluate an MBCT intervention manual specifically for people with cardiovascular disorders and mood problems.

1.9 Heart and Living Mindfully (HeLM) phases

The Heart and Living Mindfully (HeLM) project is aimed at adapting standard MBCT, so as to meet some of the needs of people with depression and cardiovascular disorders better. This project has been following the Medical Research Council (MRC) framework (Craig et al., 2008) and the NIH stage model (Onken et al., 2014) regarding complex intervention development and evaluation.

The MRC framework identifies four key elements for improving and evaluating complex interventions. The first, is the development phase that includes identifying the existing evidence base and recognising or developing appropriate theory. The second key element pertains to assessing the feasibility and piloting methods through

qualitative or quantitative studies or a mixture of both. The third and fourth key elements involve evaluating the intervention (e.g., assessing the effectiveness and understanding process) and implementation. The NIH stage model proposes six stages. Stage 0 refers to conducting basic research aimed at providing a base for developing a new intervention or refining an existing one. Studies considering how and for whom the intervention works are considered as basic research in this model. Stage 1 includes two phases: a) activities aimed at improving or refining the intervention (e.g., identifying promising clinical or basic results); and b) piloting the intervention. The other four stages are stage II (testing the intervention in research settings), stage III (testing the intervention in community clinics), stage IV (testing the effectiveness of the intervention in community settings) and stage V (implementation and dissemination).

Consequently, in line with the MRC guidelines and NIH stage model, the project was planned with three phases (see Figure 1.1). The first phase was aimed at establishing the evidence base (basic research stage) by carrying out three pieces of work (for previous phases please see Appendix A). A systematic review of the mechanisms of action in MBCT and MBSR for people with physical and/or psychological conditions was carried out. Given the awareness obtained from the first systematic review (Abbott et al., 2014) conducted in the early phase of this project that there have been very few studies that have examined MBCT/MBSR with cardiovascular disorders, the intention was to include physical conditions and not just CVDs. This systematic review was conducted to gain understanding as to how MBCT and MBSR interventions work in terms of physical/psychological conditions, so as to be able to maximise their effects for people with those conditions. More details about this review are presented in Chapter 2.0.

Second, a secondary analysis of a big randomised controlled trial looking at the impact of MBCT on medical symptoms was conducted. The aim of this study was to see whether standard MBCT could help people with physical symptoms and whether these symptoms would moderate effects of standard MBCT compared to other treatments. The findings of this study are presented in Chapter 3.0.

With regards to refining the intervention (MRC development phase and NIH model stage 1, phase A), the original MBCT manual was adapted for people with cardiovascular disorders and depression by a panel comprising experts on MBCT and physical conditions as well as people from the Public and Patient Involvement group (PPI group). Additionally, two manual development pilot groups were conducted. The second manual development pilot group comprised the first experimental study of this PhD. A detailed description of the manual development stages and the second pilot group is presented in Chapter 4.0.

In terms of addressing the second key element of the MRC framework regarding piloting and feasibility (stage1, phase B in the NIH model), a randomised controlled trial on the feasibility and acceptability of mindfulness-based cognitive therapy for people with depression and cardiovascular disorders was conducted. The aim of this study was to see whether it was feasible to conduct a definitive RCT of adapted-MBCT and whether the new course was acceptable to this population. This feasibility randomised controlled trial and the acceptability interviews are presented in Chapter 5.0.

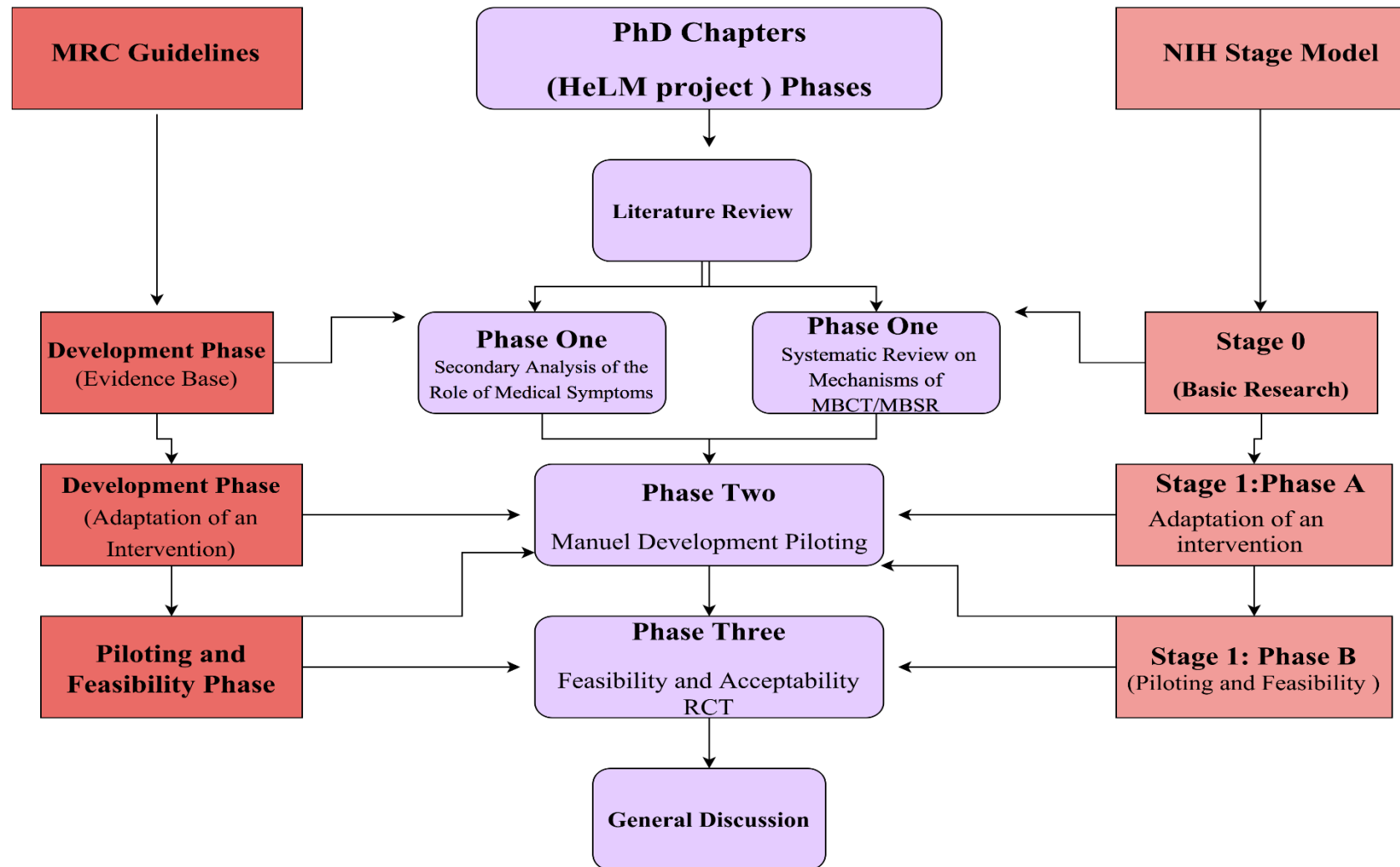


Figure 1.1 Flowchart for the PhD (HeLM Project) Phases

Chapter 2.0

Study 1

Mechanisms of Action in Mindfulness-Based Cognitive Therapy (MBCT) and Mindfulness-Based Stress Reduction (MBSR) in People with Physical and/or Psychological Conditions: A Systematic Review (Clinical Psychology Review, 55, 2017)

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2.1 Abstract

Background: Recently, there has been an increased interest in studying the effects of mindfulness-based interventions for people with psychological and physical problems. However, the mechanisms of action in these interventions that lead to beneficial physical and psychological outcomes have yet to be clearly identified.

Purpose: The aim of this paper is to review, systematically, the evidence to date on the mechanisms of action in mindfulness interventions in populations with physical and/or psychological conditions.

Method: Searches of seven databases (PsycINFO, Medline (Ovid), Cochrane Central Register of Controlled Trials, EMBASE, CINAHL, AMED, clinicaltrials.gov) were undertaken in June 2014 and July 2015. We evaluated to what extent the studies we identified met the criteria suggested by Kazdin for establishing mechanisms of action within a psychological treatment (2007, 2009).

Results: We identified four trials examining mechanisms of mindfulness interventions in those with comorbid psychological and physical health problems and 14 in those with psychological conditions. These studies examined a diverse range of potential mindfulness mechanisms, including mindfulness and rumination. Of these candidate mechanisms, the most consistent finding was that greater self-reported change in mindfulness mediated superior clinical outcomes. However, very few studies fully met the Kazdin criteria for examining treatment mechanisms. **Conclusion:** There was evidence that global changes in mindfulness are linked to better outcomes. This evidence pertained more to interventions targeting psychological rather than physical health problems. While there is promising evidence that MBCT/MBSR intervention effects are mediated by hypothesised mechanisms, there is a lack of methodological rigour in the field of testing mechanisms of action for both MBCT and MBSR, which precludes definitive conclusions.

Keywords: MBCT, MBSR, Mechanisms, Physical conditions, Psychological conditions, Systematic review

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Conflict of interest

WK is Director of the Oxford Mindfulness Centre and until 2015 was an unpaid Director of the Mindfulness Network Community Interest Company. He is the Principal Investigator of several externally funded projects evaluating the efficacy of MBCT. All other authors have declared that they have no conflict of interest

Authors' contributions

MA drafted the review protocol, conducted the database searches, carried out the screening of the identified studies, evaluated the included studies and drafted the manuscript. WK contributed to the review protocol, developed the review framework, checked the evaluation of the included studies and reviewed the manuscript. RA contributed to the review protocol, checked the screening and evaluating studies as well as reviewing the manuscript. BD and CD contributed to the design of the protocol and reviewed the manuscript. WH commented on the manuscript. TK helped with database searches and screening the identified studies. All the authors have approved the final manuscript.

2.2 Background

Long-term physical and mental health problems affect a significant proportion of the population, place an enormous burden on health care systems, are a very significant cost to society and cause immeasurable suffering. It is estimated that 46 % of people in the UK with mental health problems also suffer from long-term physical conditions, such as heart conditions, stroke, diabetes and cancer (Naylor et al., 2012). This comorbidity is responsible for poor medical outcomes (Katon, 2011; Kisely, Smith, Lawrence, & Maaten, 2005; Wright et al., 2008), significant decrements in quality of life (Fortin et al., 2006; Moussavi et al., 2007; Sareen. et al., 2006) and increased costs of health care (Naylor et al., 2012). Therefore, there is a need to develop integrated treatments that can effectively treat people with comorbid mental and physical health presentations. It is increasingly argued that there could be some overlap in the biological, behavioural and psychosocial mechanisms linked to these physical and psychological conditions (Carlson, 2012; DE Hert et al., 2011; Dickens, 2015; Miller, Chen, & Cole, 2009). Consequently, researchers are increasingly trying to develop integrated mind-body theoretical models that can potentially capture the shared mechanisms and support the development of effective treatments for physical conditions that have mental health comorbidity.

Mindfulness-based interventions were developed for people with chronic physical problems, who were managing pain, low mood and health-related anxiety. Mindfulness is most typically defined as “paying attention in a particular way: on purpose, in the present moment, and non-judgementally” (Kabat-Zinn, 1994, p. 4). An operational definition of mindfulness would include at least three components: attentional control, the intention of attentional control (e.g., to decenter from negative

thinking) and attitudes that are being trained (e.g., approach orientation and non-judgment).

Mindfulness-Based Stress Reduction (MBSR) has been used since 1979 as a training vehicle for the relief of pain and distress in people with chronic health problems (Kabat-Zinn, 1990, 2013). Mindfulness-Based Cognitive Therapy (MBCT) (Segal, Williams, & Teasdale, 2013; 2002) integrates MBSR with cognitive science and Cognitive Behavioural Therapy. It was initially developed as a relapse prevention treatment in those with a high risk of depression recurring, but has since been adapted to a range of different populations and contexts. Both MBSR and MBCT incorporate a range of formal mindfulness practices as a key method for training attentional control as well as the non-judgemental attitudinal dimensions of mindfulness (Crane et al., 2017).

MBSR has been found to have positive effects on pain, anxiety and stress in people with chronic disorders, such as fibromyalgia, coronary artery disease, back pain and arthritis (Grossman, Niemann, Schmidt, & Walach, 2004; Rosenzweig et al., 2010). Preliminary evidence suggests that MBCT can decrease depression, anxiety and fatigue in some physical conditions, such as coronary heart disease (O'Doherty et al., 2015), diabetes (van Son et al., 2014; Van Son, Nyklíček, Pop, & Pouwer, 2011) and cancer (Van Der Lee & Garssen, 2012). Moreover, recent systematic reviews have indicated that MBSR and MBCT have small to medium effect sizes on psychological and physical symptoms across a range of chronic somatic conditions including cancer, cardiovascular disorders and arthritis (Abbott et al., 2014; Bohlmeijer, Prenger, Taal, & Cuijpers, 2010; Hofmann, Sawyer, Witt, & Oh, 2010).

In addition to research evaluating clinical efficacy, there is also a need to understand the mechanisms of action of these mindfulness interventions (Craig et al., 2008; Moore, Audrey, Barker, & Bond, 2014). A greater understanding of the

mechanisms through which interventions bring about change will enable these interventions to be refined, which will potentially increase their potency and provide “larger effect sizes at lower cost or risk” (Kraemer, Wilson, Fairburn, & Agras, 2002, p. 878). Moreover, it will shed light on the theories that explain how these conditions arise.

A mechanism is defined as “the process that is responsible for change”, while a mediator is “an intervening variable that may account statistically for the relationship between independent variable and dependent variable” (Kazdin, 2007, p. 3). Kazdin (2007, 2009) proposes essential criteria for identifying mechanisms or mediators of action in psychotherapy. To begin with, there needs to be a clear association between change in the proposed mechanism/mediator and the proposed outcome (strong correlation criterion). In addition, the outcomes and mediating variables need to be measured at multiple time points, thus making it possible to establish that change in the mediator precedes change in the outcome (temporal precedence criterion). Manipulation designs (where a specific mechanism is increased or decreased), active and/or dismantling designs (where intervention elements targeting a specific mechanism are left out) need to be utilised to determine the specificity of effects (specificity criterion). Further, a dose-response relationship needs to be observed, such that the more a mechanism is targeted, the greater the degree of change in the outcome observed (gradient criterion). The findings should be replicable; ideally by an independent research group (consistency criterion). Kraemer and colleagues suggest that randomised controlled trials (RCTs) are needed to test the mechanisms or mediators routinely and that experimental studies need to take into account the RCTs results in their designs (Kraemer et al., 2002).

There is as yet no consensually agreed unifying theoretical framework of how MBCT/MBSR effect change, but rather a breadth of theoretical models. A recent

editorial suggested that there is some consensus that MBCT/MBSR helps people ‘learn that habitual reactive patterns stem from unhelpful habits of the mind; that fear, denial and discrepancy-based thinking create and exacerbate distress; and that skilful ways of relating to experience can be developed through awareness, wise discernment and practice which offer the potential for (moments of) freedom from reactivity’ (Crane et al., 2017).

Several early studies have started to explore the mechanisms in MBCT/MBSR (Batink, Peeters, Geschwind, van Os, & Wichers, 2013; Geschwind, Peeters, Drukker, van Os, & Wichers, 2011; Nyklíček & Kuijpers, 2008; Vøllestad et al., 2011). To date most mechanisms studies have either not explicitly drawn on a particular theoretical model or have drawn on different models and selected out particular mechanisms and defined these with varying degrees of precision. Moreover, they have failed to employ robust designs to assess the proposed mechanisms (Gu et al., 2015; van der Velden et al., 2015).

It is as yet unclear whether mechanisms of action in MBCT/MBSR are shared across physical and psychological health conditions or are specific to particular physical or psychological health conditions. Some researchers think that there are potential common or universal mechanisms of action in MBCT/MBSR regardless of whether the specific disorder is physical (Carlson, 2012) or psychological (Teasdale, Segal, & Williams, 2003). A narrative review (Carlson, 2012) of mindfulness interventions in physical conditions has indicated that mechanisms such as mindful attention, acceptance and exposure are important in understanding how MBCT/MBSR are effective for different physical conditions. Other researchers suggest that some mechanisms of action are disorder-specific. For example, Loucks and his colleagues in their recent review (Loucks et al., 2015) put forward some mechanisms that might explain how mindfulness

works with cardiovascular disorders (CVD), including attentional control of some of the risk factors of CVD and self-awareness of cardiac experiences that are potentially modifiable.

The delineation of universal and specific vulnerabilities that may also be mechanisms of change leads to the generation of key hypotheses that can inform both primary research and interpretation of secondary research (Teasdale et al., 2003). In terms of vulnerability, unhelpful repetitive thinking hijacking attention could be universal (Watkins, 2008), while in people with a history of depression cognitive reactivity, characterised by negative self-referential thoughts, might be a specific vulnerability (Segal et al., 2013). In terms of the hypothesised mechanisms, learning to stabilise attention (a universal mechanism), which refers to our capacity to cultivate and stabilise or focus attention in the body (Williams & Kabat-Zinn, 2013), could be a pre-requisite to first recognising cognitive reactivity (a specific mechanism in this population) and then decentering from negative thinking (an emotion regulation strategy). Cognitive reactivity is defined as ‘the degree to which a mild dysphoric state reactivates negative thinking patterns’ (Raes, Dewulf, Van Heeringen, & Williams, 2009, p. 623)

Recently, Van der Velden et al. (2015) conducted a systematic review of the mechanisms of MBCT in RCTs looking at how MBCT produced its effects on both relapse prevention and acute depression in people with major depressive disorders (MDD). The results showed good evidence supporting the mediating role for mindfulness, rumination, worry, compassion, meta-awareness with preliminary evidence for attention, memory specificity, self-discrepancy, emotional reactivity as well as positive and negative affect. This review only considered MDD not physical conditions and primarily focused on depression outcomes. Although, the review mentioned some of

the Kazdin criteria, it did not systematically evaluate each study against these. Another recent systematic review and meta-analysis, conducted by Gu et al. (2015), tested the mechanisms of both MBSR/MBCT on mental health and wellbeing outcomes, including for those with primary physical health problems (e.g., cancer). In this review, RCTs or quasi-experimental design studies were included, and they found strong evidence for cognitive and emotional reactivity, moderate evidence for mindfulness, rumination, and worry as potential mechanisms of change, and preliminary but insufficient evidence for self-compassion and psychological flexibility. This review involved using a well-established method of mediation analysis and had a quantitative assessment of change in the outcome and mediators. However, the review had some limitations, such as not considering the methodological quality, not commenting on the Kazdin's criteria in detail and considering only mechanisms with a strong theoretical rationale, thus excluding some potential more exploratory variables. In addition, even though the review targeted a broad range of populations, including people with cancer, it did not focus on whether the same mechanisms play a role in depression versus depression in the context of long term conditions.

There is therefore a need for a further systematic review of mechanisms of action in mindfulness interventions that deals with these shortcomings. In this review, we further explored the evidence, to date, on mechanisms of action in MBCT/MBSR interventions for populations with physical and/or psychological conditions. We included studies that focused on populations with physical and/or psychological conditions to assess whether the evidence for mechanisms accounting for psychological symptom improvement has been found both in those with psychological and physical health presentations. We looked at whether the same mechanisms have been identified across different populations (primarily depression or primarily physical health), which would

suggest they may be universal. Also, we aimed to assess methodological adequacy of these studies according to the Kazdin criteria for examining mechanisms of change in treatments. We approached the mechanisms of action in an exploratory (rather than theory driven) way, that is, simply identifying and reporting the mechanisms/mediators that were reported in the identified studies. Moreover, we considered the recommendations mentioned in Gu and her colleagues (2015) review in terms of publication bias and variation in the nature of the outcome variable (acute versus relapse prevention; physical or psychological). The aim of this work is to usefully frame future primary research.

2.3 Method

2.3.1 Inclusion and Exclusion Criteria

The systematic review was conducted following the general principles published by the NHS Centre for Reviews and Dissemination (CRD, 2009) and reported according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (Moher, Liberati, Tetzlaff, & Altman, 2009). It included published randomised controlled trials (RCTs), and controlled trials (CTs) that aimed to examine potential mechanisms or mediators of change in MBCT/MBSR in adults diagnosed with physical and/or psychological conditions. Studies using shortened forms of either MBCT or MBSR were excluded. No language or date restrictions were applied for this review. Details of the inclusion and exclusion criteria are presented in Table 2.1

2.3.2 Identification of Studies

2.3.2.1 Search strategy.

The first electronic search of seven databases (PsycINFO, Medline (Ovid), Cochrane Central Register of Controlled Trials, EMBASE, CINAHL, AMED, clinicaltrials.gov) was undertaken in June 2014 and we conducted an update search in

July 2015. The search strategy varied across the databases, but the same keywords applied throughout. An example of the search strategy is presented in Appendix B.

2.3.2.2 Study selection.

After removing duplicates, the titles and abstracts were screened independently by MA and TK, with the aim of identifying potentially relevant studies. During this phase, inclusion and exclusion criteria were applied and disagreement was resolved through discussion with a third reviewer, RA. Subsequently, full texts of the promising studies were obtained, and their reference lists were examined by MA. In the second phase of screening, the full texts were assessed further for eligibility by MA and checked by RA.

2.3.2.3 Data extraction.

We collected the characteristics of studies using the PICOS (Population, Intervention, Comparator, Outcomes and Study design) framework. The population features included age, gender, sample size and whether it was a psychological or physical condition. Intervention covered whether the intervention used was MBCT or MBSR and if had been administered as its developers had intended or had been adapted. Comparator features consisted of the number of study arms and type of control group (waitlist, other active intervention or treatment as usual). The outcomes pertained to the main findings in terms of physical and/or psychological aspects, whilst the study design included whether it was a randomised controlled trial (RCT) or a controlled trial (CT). We additionally extracted all information that would enable us to evaluate how well the Kazdin criteria (2007, 2009) were met. Data extraction was conducted by MA and checked by RA.

2.3.2.4 Data synthesis.

The aims of this review were not to examine the effectiveness or efficacy of interventions, but rather, to describe and evaluate potential mechanisms or mediators.

We anticipated identifying studies that used a range of different interventions, with possible different mechanisms or mediators of action in different populations. We anticipated that pooling the data would distract from the main aims of the review, would be difficult to interpret, and would not add value. Therefore, where sufficient data was available we decided to classify data by population type and then evaluate the status of the evidence for each hypothesized mechanism/mediator within each population type.

2.3.3 Risk of Bias in RCTs

The methodological quality of each included study was assessed using the Cochrane ‘risk of bias’ tool (Higgins et al., 2011). Each study was evaluated based on certain parameters, such as random sequence generation, allocation concealment, blinding and selective reports. The risk of bias in the RCTs’ evaluation was conducted by MA and checked by RA.

2.3.4 Conceptual Framework for Abstracting and Interpreting Studies

We developed a framework derived from the recommendations put forward by Kazdin (2007, 2009), which both informed the data extraction and the interpretation of the findings. This framework included the following questions:

1. Did the study use a theory or treatment rationale to articulate the mechanism through which the intervention is hypothesised to work? This includes:
 - Were hypotheses about the mechanism of change articulated?
 - Were the hypothesised processes of change articulated, defined and operationalised?
2. Did the study use process measures that assess the constructs, if necessary, from a variety of perspectives? A variety of perspectives means here the study’s use of a variety of assessment methods in addition to self-report measures, which could include experimental or neuroscience measures”.

3. Did the study design ensure the hypotheses could be addressed? This includes:
 - Making explicit that changes in processes are specifically targeted by the treatment;
 - That changes occur during treatment;
 - That these changes precede change in the outcome;
 - Using different time-points assessments.
4. Did the study use appropriate statistical analysis?

2.4 Results

2.4.1 Studies Flow

The electronic searches of seven databases retrieved 3,290 titles and abstracts. After adjusting for duplicates and reviewing the titles and abstracts, 3,234 studies were removed. In the first phase of the screening for eligibility, 56 abstracts and titles were screened against the inclusion and exclusion criteria, resulting in 15 studies being excluded for the following reasons: five were not MBCT or MBSR, two focused on healthy populations, two were short MBSR (six weeks), four did not examine mechanisms or mediators and two were not randomised controlled trials or controlled trials. In the second phase, 35 of the 41 full texts were obtained while six were conference abstracts rather than published papers and the necessary information was not available. The 35 full texts were screened further against the inclusion and exclusion criteria. In this phase, 17 studies were excluded for the following reasons: four for not being MBCT or MBSR, four focused on healthy populations, four used short MBSR (four-six weeks), three were not randomised controlled trials or controlled trials, one did not examine mechanisms or mediators and one tested moderators of MBCT. Finally, four studies with physical conditions populations and 14 studies with psychological conditions populations met the inclusion criteria of this review (see Figure 2.1).

2.4.2 Studies Focused on Populations with Physical Conditions

2.4.2.1 Characteristics of the studies.

Table 2.2 summarises the characteristics of the included studies that focused on people with physical conditions and co-existing psychological problems. Four studies met the review criteria: three focused on people with cancer (Bränström, Kvillemo, Brandberg, & Moskowitz, 2010; Labelle, Campbell, & Carlson, 2010; Labelle, Campbell, Faris, & Carlson, 2015) and one (O'Doherty et al., 2015) targeted people with coronary heart disease (CHD). One study (Bränström et al., 2010) employed an RCT design and three used a CT design (Labelle et al., 2010, 2015; O'Doherty et al., 2015). All the studies compared MBSR/MBCT to waitlist control. The sample sizes ranged from 71 to 211 with a total of 71 randomised and 405 non-randomised. Two studies included only females ($n = 147$) (Bränström et al., 2010; Labelle et al., 2010).

Two out of the four included studies examined more than one mediator, which were mindfulness skills ($n = 4$), rumination ($n = 2$) and cancer-related worry ($n = 1$). All the studies used self-report questionnaires to assess the proposed mediators. Three (Bränström et al., 2010; Labelle et al., 2010, 2015) made some adaptations to the MBSR original manual so as to make it appropriate for people with cancer, but with the same length of course, whilst the only study that used MBCT followed the programme as outlined by Segal et al. (2002, 2013).

2.4.2.2 Mechanisms/mediators in studies with physical conditions populations.

2.4.2.2.1 Mindfulness, rumination and worry. Mindfulness, as a potential mediator, was tested in the all of these studies and rumination was assessed in two. Of the four studies looking at mindfulness as the mediator, two (Bränström et al., 2010; O'Doherty et al., 2015) showed it mediated the effects of MBCT/MBSR on perceived

stress, posttraumatic avoidance, positive state of mind, current depression, anxiety, psychosocial adjustment to illness, mood and health-related quality of life. In these studies, mindfulness was assessed by different measures that have different conceptual backgrounds. For example, the Kentucky inventory of mindfulness (KIMS) (Baer, 2004) and five-facet mindfulness questionnaire (FFMQ) (Baer et al., 2006, 2008) were developed based on the assumption that mindfulness is a multifaceted construct, including facets such as observing, describing, acting with awareness, non-judgment and non-reactivity, while the mindful attention awareness scale (MAAS) was developed with a single-factor structure (receptive attention to and awareness of present events and experience) (Brown & Ryan, 2003). The other two studies (Labelle et al., 2010, 2015) found no mediation effect of mindfulness on depression, experiential avoidance and stress symptoms. Both studies (Labelle et al., 2010, 2015) that assessed rumination as a mediator found it to be a significant mediator of MBSR for depression, experiential avoidance and stress symptoms (Labelle et al., 2010, 2015).

Bränström and his colleagues (2010), in their RCT with two time-points (pre-post), tested whether mindfulness skills would mediate the effects of adapted-MBSR in females with cancer ($n = 71$). The results indicated that the positive effects of the MBSR intervention on stress, posttraumatic avoidance and positive states of mind were mediated by significant increases in mindfulness skills. A study by O'Doherty et al. (2015) used a controlled trial with three time-points (pre-post-follow up) to evaluate the effectiveness of MBCT on people with coronary heart disease (CHD) and current depression, and test whether mindfulness would lead to changes in outcomes. The results revealed that the MBCT group when compared to the waiting list group showed improvements for current depression, anxiety, psychological adjustments to illness,

quality of life and mindfulness, with these improvements being correlated significantly with the increases in mindfulness.

Labelle et al. (2010) in a controlled study of 77 females with cancer using two time- points, found that mindfulness did not mediate the significant effect of adapted-MBSR on depressive symptoms, while rumination did. Consistent with this result, a recent controlled study (Labelle et al., 2015) with three time-points (pre, mid, and post intervention), showed that early decreases in rumination and cancer-related worry mediated the effects of adapted-MBSR on the outcomes, while mindfulness skills did not.

2.4.3 Studies Focused on Populations with Psychological Conditions

2.4.3.1 Characteristics of studies.

Table 2.3 shows the characteristics of the included studies that focused on people with psychological conditions (depression and anxiety). 14 published trials met the review criteria, three of which used the same dataset (Batink et al., 2013; van Aalderen et al., 2012; van den Hurk et al., 2012). All the studies employed an RCT design. The sample sizes ranged from 29 to 219 with a total of 1,122 randomised males and females. Four studies compared MBCT to treatment as usual (TAU), four compared MBCT ($n = 3$) or MBSR ($n = 1$) to waitlist, three studies compared MBSR to active groups (aerobic exercise, stress management), one compared MBCT plus discontinuation of antidepressant medication to maintenance antidepressant medication (m-ADM), one study used the depression relapse active monitor (DRAM) as a control group and one had three arms: MBCT, m-ADM and a placebo. Among the depression studies, the majority focused on recurrent MDD, whereas one (van Aalderen et al., 2012) targeted recurrent and current depression. The studies used different criteria to establish MDD, such as the Structured Clinical Interview for DSM-IV (SCID) and the Hamilton Rating

Scale for Depression (HRSD). All studies followed the MBCT/MBSR programmes, as outlined by Segal et al. (2002, 2013) and Kabat-Zinn (1990, 2013).

The majority of the studies ($n = 11$) examined two or more mediators. Those examined included mindfulness skills ($n = 8$), rumination ($n = 5$), positive affect ($n = 2$), worry ($n = 2$), cognitive function and reactivity ($n = 2$), emotional reactivity ($n = 1$), attentional processes ($n = 1$), self-compassion ($n = 1$), decentering ($n = 2$), self-referential brain network ($n = 1$), brain activation and connectivity ($n = 1$). With regard to measuring the mediators, the majority of the studies ($n = 10$) relied on self-report. Emotional and cognitive tasks in addition to self-report measures were used to assess attentional processes as well as emotional and cognitive reactivity ($n = 3$), whilst two studies used fMRI.

2.4.3.2 Mechanisms/mediators in studies with psychological conditions populations.

2.4.3.2.1 Anxiety disorders.

2.4.3.2.1.1 Mindfulness and decentering. Two studies examined mindfulness as the mechanism of change for MBSR in people with anxiety disorders. Vøllestad, Sivertsen, and Nielsen (2011) looked at mindfulness as a mediator of the relationship between MBSR and improvements in anxiety, worry and depression in a randomised controlled trial for people with anxiety disorders. The results indicated that during MBSR significant increases in mindfulness skills mediated the relationship between MBSR and anxiety and worry, but not depression when compared to waitlist control. Another randomised study (Hoge et al., 2015) that compared adapted-MBSR to stress management education (SME) in people with generalised anxiety disorders (GAD), found that a significant increase in decentering was a mediator for MBSR in relation to anxiety, while significant increases in mindfulness skills mediated the effects of MBSR

on worry when compared to a stress management group. In this study, decentering is defined as “a metacognitive capacity of individuals to observe items that arise in the mind (e.g., thoughts, feelings, memories, etc.) as mere psychological events” (Hoge et al., 2015, p. 229).

2.4.3.2.1.2 Brain network and connectivity. Goldin, Ziv, Jazaieri, & Gross (2012) tested the correlation between self-referential brain networks and improvements in social anxiety symptoms in people undertaking MBSR compared with a group undertaking aerobic exercise (AE). The fMRI and self-referential encoding task results showed that significant changes in self-views as well as dorsomedial pre-frontal cortex (DMPFC) activity during negative self-view were correlated with significant reductions in social anxiety in the MBSR group. Hölzel et al. (2013) found that people undergoing MBSR, when compared to a stress management group, showed changes in ventrolateral prefrontal regions (VLPFC) activation and amygdala–prefrontal connectivity and these were associated with improvements in generalised anxiety disorder.

2.4.3.2.2 Depression.

2.4.3.2.2.1 Mindfulness. Six RCTs indicated that MBCT led to a significant decrease in residual depressive symptoms (Batink et al., 2013; Bieling et al., 2012; Kuyken et al., 2010; Shahar, Britton, Sbarra, Figueredo, & Bootzin, 2010; van Aalderen et al., 2012) and relapse (Kearns et al., 2015; Kuyken et al., 2010). These effects were found to be mediated by significant increases in overall mindfulness (Kearns et al., 2015, Kuyken et al., 2010; Shahar et al., 2010), acceptance without judgment (Batink et al., 2013; van Aalderen et al., 2012) and curiosity (Bieling et al., 2012).

2.4.3.2.2.2 Rumination. Rumination refers to “a mode of responding to distress that involves repetitively and passively focusing on symptoms of distress and on the possible causes and consequences of these symptoms”(Nolen-Hoeksema, 1991, p. 1).

Two MBCT studies indicated that significant reductions in depression were mediated by rumination (van Aalderen et al., 2012) and brooding as a component of rumination (Shahar et al., 2010), while the outcomes of other studies have determined that the effects of MBCT were not mediated by rumination as a total score (Batink et al., 2013; Bieling et al., 2012; Kearns et al., 2015) or reflective pondering, as a component of rumination (Shahar et al., 2010).

2.4.3.2.2.3 Worry, affect and self-compassion. Worry refers to “a chain of thoughts and images that are affectively negative and relatively uncontrollable” (Borkovec, Robinson, Pruzinsky, & DePree, 1983. p. 10). Two MBCT studies using the same dataset (Batink et al., 2013; van Aalderen et al., 2012) tested worry as a proposed mediator of change by using self-report measures and found that it mediated the effects of MBCT on depressive symptoms. Regarding affect, two studies assessed whether increased positive affect acted as a mediator of the effect of MBCT on depression, using experience sample methods (ESM). The first (Geschwind, Peeters, Drukker, van Os, & Wichers, 2011), showed that increased positive affect (PA), activity pleasantness, and reward experience (SE) were associated with decreases in depression. The second (Batink et al., 2013), found that an increase in positive affect and a decrease in negative affect were mediated MBCT effects on depression. In another study, learning self-compassion was found to have a mediating role in the relationship between MBCT participation and depression over a 15 months follow up period (Kuyken, Watkins, et al., 2010). Self-compassion is defined as “being touched by and open to one’s own suffering, not avoiding or disconnecting from it, generating the desire to alleviate one’s suffering and to heal oneself with kindness” (Neff, 2003, p. 87).

2.4.3.2.2.4 Cognitive and emotional reactivity. Kuyken et al. (2010) found that high levels of cognitive reactivity predicted a poorer outcome in terms of depressive

symptoms and relapse rate in the m-ADM group, but for the MBCT group this link between reactivity and outcome was weakened. With regards to emotional reactivity which is defined as “progressively prolonged or intensified negative affect in response to stress” (Britton et al., 2012, p. 366), Britton, Shahar, Szepsenwol, & Jacobs (2012) conducted a laboratory study to test emotional reactivity to a social stress task in people with recurrent depression. The results indicated that improvements in emotional reactivity mediated the relationship between MBCT and depression.

2.4.3.2.2.5 Cognitive function and attentional processing. Jermann et al. (2013)

examined five cognitive functions (autobiographical memory, shifting abilities, dysfunctional attitude, mindful attention and rumination), using a combination of cognitive tasks and self-report measures. They found that the participants in the MBCT group showed a significant decrease in dysfunctional attitudes at 9 months follow up. Van den Hurk and colleagues (2012) tested different components of attentional processing (alerting, orienting and executive attention) by using an attentional network test. The results indicated that MBCT led to reductions in depression and rumination and increases in mindfulness skills when compared to TAU, but no significant differences in components of attention between MBCT and TAU were found. In terms of testing the mediating role of attentional processing, the results suggested that attentional processing did not mediate the relationship between MBCT and depression when compared to the TAU group.

2.4.4 Risk of Bias in the RCTs

Risk of bias assessments are shown in Tables 2.4 and 2.5. Regarding the studies with physical conditions populations, the majority had shortcomings regarding sequence generation and allocation concealment. However, most did adequately describe eligibility criteria and data collection tools valid. For the studies regarding psychological

conditions, the majority adequately described sequence generation, allocation concealment and selective reporting. These studies also effectively reported eligibility criteria, power calculations, compliance with intervention and data collection tools valid.

2.4.5 Evaluating the Ability of the Studies to Assess Mechanisms or Mediators

Each study was also evaluated based on our previously mentioned framework (see Tables 2.6 and 2.7). In this section, we present, first, whether each included study was able to meet the eight criteria of this review framework and then, we report how well all of them met the four questions that represent the eight criteria.

With regards to the studies pertaining to physical conditions, that by Bränström et al. (2010), which targeted females with cancer, met five of the eight criteria of this review, but it did not reflect different perspectives in terms of assessing mediators of MBSR. In addition, two time-point assessments were used, which meant that they were not able to prove that the change in their proposed mediator (mindfulness skills) preceded the observed changes in the study outcomes. The study by Labelle et al. (2010) that also studied females with cancer met five criteria, but could not meet 3, 6 or 7. The authors relied on self-report measures to assess their mediators (mindfulness and rumination) and used two time-points, which meant that temporal precedence could not be established and therefore, true mediation could not be tested. Labelle and her colleagues in their recent study (2015) with people with cancer met seven criteria however, they used only self-report measures to assess rumination, mindfulness skills and worry as proposed mediators of the effects of MBSR. The study by O'Doherty et al. (2015) that focused on people with coronary heart disease met six criteria, but did not satisfy 3 and 8. The correlation analysis that was used in this study was not able to test the full mediation of effects of MBCT on depression.

Regarding the studies focussed on psychological conditions, the studies that targeted people with anxiety disorders (Goldin et al., 2012; Hoge et al., 2015; Hölzel et al., 2013; Vøllestad et al., 2011) met between five and six of the eight criteria. These studies used two assessments, hence being unable to show the temporal precedence between mediators and outcomes. In terms of studies that targeted people with depression using MBCT, Kuyken et al., (2010) met all the eight criteria of this review framework, whilst others (Bieling et al., 2012; Kearns et al., 2015) met seven and could not meet criterion 3. The studies by Batink et al. (2013), Shahar et al. (2010), van Aalderen et al. (2012) van den Hurk et al. (2012) met five criteria and had limitations in term of relying on self-repost measures, using just two time-points and not showing the temporal precedence. The studies by Geschwind et al. (2011) and Jermann et al. (2013) met between four and five of the eight criteria, not being able to satisfy criteria 6,7, 8, having shortcomings in terms of not using enough time point assessments, not showing the temporal precedence and not using the appropriate statistical analyses.

2.4.5.1 Did the study use a theory?

The mechanisms need to be identified based on a theory or treatment rationale for articulating the mechanisms through which the treatment is hypothesised to work (Kazdin, 2007). While all studies reported using some theory, very few articulated a coherent account of universal and/or specific vulnerabilities driving the problems or explained exactly how MBCT/MBSR would target these mechanisms. We found that the studies with participants with physical conditions, especially those focusing on cancer populations, represented good attempts to develop models that linked mindfulness and emotions regulation as mediators for MBSR effects on cancer. There is a need for further studies that consider clearly articulated mechanisms, such as those proposed in reviews conducted by Carlson et al. (2012) and Loucks et al. (2015). With regards to studies

focussed primarily on psychological conditions, the majority with depression populations used a well-designed theoretical model of MBCT intervention for recurrent depression. However, many looked at a single mediator and did not consider the issue of universal versus specific vulnerabilities or the inter-play between different mechanisms.

2.4.5.2 Did the study use process measures that assess the constructs, if necessary, from a variety of perspectives?

The use of measures that can consider different viewpoints, such as experimental and neuropsychological measures, is another important matter that needs to be considered (Kazdin, 2007). All the included studies used some form of measures to assess the mediators; however, there was wide variability in the types used. We found that the studies of physical conditions ($n = 4$) relied completely on self-report measures to assess mediators, such as mindfulness, rumination and cancer-related worry. In the studies of psychological conditions, whilst the majority ($n = 10$) used self-report measures, we did find some examples of more objective measures, such as fMRI and laboratory tests, to assess self-referential brain network, brain connectivity as well as emotional and cognitive reactivity.

2.4.5.3 Did the study design ensure the hypotheses can be addressed?

It is worth noting that the best design is one that can assess changes over different time points within an RCT design (Kazdin, 2007). Even though most the studies ($n = 15$) were RCTs, which is considered as the gold standard for testing efficacy and effectiveness, the number of time assessments included in these was not optimal to for testing mechanisms or mediators. Only two of the five studies focusing on populations with physical conditions (Labelle et al., 2015; O'Doherty et al., 2015) and three of the depression and anxiety studies (Bieling et al., 2012; Kearns et al., 2015; Kuyken, Watkins, et al., 2010) used three or more time points.

The majority of the studies looked at changes from Time 1 to Time 2 in both constructs, meaning temporal precedence (change from Time 1 to Time 2 in the mediator predicts change between Time 2 and Time 3 in the outcome) could not be established (and reverse causality remained a possibility). However, all the studies in this review failed to assess the changes over several time points.

2.4.5.4 Did the study use appropriate statistical analyses?

Some statistical criteria have been suggested that can help in testing mediation effects (Kazdin, 2007, 2009; Kraemer et al., 2002). For example, establishing significant relationships between the intervention, the proposed mediator and the outcome, as well as between the proposed mediators and the outcomes. Another important criterion is establishing the precedence between the changes in mediators and changes in outcomes. In this review, we found that whilst the majority of studies used some form of mediation analyses, the rest employed analyses that could not test mediation. Moreover, it was not possible to conduct a full test for mediation due to insufficient time points in many of the studies.

2.5 Discussion

In this review, we first aimed to review the potential mechanisms of change in MBCT and MBSR for people with physical and/or psychological conditions. A second aim was to see whether there are universal mechanisms of mindfulness interventions that apply across populations/conditions as well as specific mechanisms that pertain to a particular population/condition. The evidence from the included studies was evaluated based on Kazdin's framework (Kazdin, 2007, 2009). The results of the review are consistent with the two recent reviews (Gu et al., 2015; van der Velden et al., 2015). While there is promising evidence that MBCT/MBSR treatment effects are mediated by hypothesised mechanisms, such as mindfulness and rumination, there is a lack of

methodological rigour in the field of testing mechanisms and mediators of action in both MBCT and MBSR that precludes definitive conclusions.

Moreover, the lack of a consensually agreed theoretical framework of what universal and specific mechanisms drive change in MBCT/MBSR means that we do not, as yet, have the basis for articulating what degree of change, in which mechanisms (e.g., orienting attention, executive control, compassion), through which components of MBCT/MBSR (e.g., particular formal mindfulness practices) drive change, with which populations (e.g., adults with recurrent depression, health related anxiety), for which aims (e.g., reduce depressive relapse). Our findings provide insights that can inform future experimental and mechanisms studies embedded in trials to better articulate these elements.

Moreover, our review highlights that less attention has been given to studying the mechanisms of change through MBCT/MBSR in populations with physical conditions when compared to populations with psychological ones. Moreover, the few studies examining physical health conditions focused primarily on psychological symptoms outcomes such as stress, anxiety and depressive symptoms and neglected physical health outcomes.

In two out of the four studies, mindfulness and rumination seem to mediate the effects of MBCT/MBSR on perceived stress, posttraumatic avoidance, depression, positive state of mind and psychosocial adjustment to illness for people with physical conditions (heart conditions and cancer). However, only one out of the four physical studies focused on mediating factors that were specifically related to the populations, namely cancer-related worry in a cancer population (Labelle et al., 2015). Examining mechanisms that are specific to a population or intervention is essential to test whether universal and specific vulnerabilities/mechanisms are being targeted.

In the studies of psychological conditions, we found that depression has received much attention with regards to mechanisms of action in MBCT, while anxiety has received most attention in relation to MBSR. The majority of the included studies considered mindfulness as a universal mediator. In most, mindfulness shows potential as a mediator of change in MBCT/MBSR for people with depression, anxiety and stress. In addition to mindfulness, rumination, worry and self-compassion have been investigated for mediation effects.

Other proposed mediators, such as attention and emotional reactivity, were assessed to a lesser degree. To assess attention and reactivity well requires experimental paradigms that the majority of the studies to date have not included. Moreover, studies sometimes used different measures of the same outcome; for example, in depression relapse some prevention studies used depressive relapse/recurrence whilst others used residual depressive symptoms as a proxy. It is possible that different mechanisms could be at play for each of these.

There was evidence that global changes in mindfulness were linked to better outcomes. This evidence pertained more to interventions targeting psychological rather than physical health problems. Some variables hold up strongly as a candidate universal mechanism or mediator of change in MBCT/MBSR across psychological and physical populations (e.g., enhancing mindfulness) whilst others seem promising as specific to particular populations (e.g., decentring from negative thinking with depression). Moreover, there may be universal mechanisms that have specific manifestations in a given population (e.g., repetitive thinking as a universal mechanism; in recurrent depression, the focus is on the causes, meanings and consequences of depression whereas in cardiovascular disorders it may be on the causes, meaning, consequences around physical health). These hypotheses need to be tested in future work.

Most studies relied on self-report measures and very few were adequately powered to examine mediation. Triangulation of measures and sufficient power will enable more exploratory examination of as yet “unknown” mechanisms. For example, the two studies that examined neuroscience mechanisms suggested particular brain networks as candidate mechanisms. These studies suggest that there could be a range of possibilities regarding how MBCT/MBSR interventions produce their effects and future work might usefully triangulate across neuroscience, experimental and self-report measures.

An important feature we highlighted in our review was the constituent studies’ design regarding the timeline of changes. In this regard, it was found that majority of studies did not establish a timeline that would provide a full test of mediation. This means that the findings of such studies regarding the role of a specific mediator are just preliminary and future research needs to ensure temporal sequencing of assessments that enables change in mechanisms to be assessed separately and temporally before change in outcomes. Many of the included studies were conducted with the primary aim of assessing the effectiveness of MBCT/MBSR interventions, with identifying mechanisms being a secondary goal. Furthermore, some studies that tested mediators in detail were post hoc analyses using datasets obtained from effectiveness studies. As discussed above, it is essential to design mechanisms studies that choose time points and time scales so as to uncover the temporal relationships between mediators and outcomes over short and long-term trajectories of change.

In most of the studies, both MBCT and MBSR demonstrated significant reductions in the proposed mediators and targeted outcomes compared to the different control groups (active, waitlist) as well as for different populations (physical and psychological). This suggests that there are associations between the intervention, the

mediator and the outcome. However, a significant relationship between the mediator and the outcome was not supported in some of the studies. This inconsistency we argue provides fertile ground for hypothesis generation that can be tested in improved study designs. Recently, there has been a growing interest in causal mediation analysis that includes methods for dealing with multiple mediators (Tingley, Yamamoto, Hirose, Keele, & Imai, 2014). Such methods should be considered in future studies aimed at testing multiple mediators. Moreover, there has been growing interest in developing models that can test what works for whom.

2.6 Strengths and limitations

This review was aimed at understanding mechanisms of change in MBCT and MBSR when used for people with physical and/or psychological conditions. This work has the potential to shed light on the theory underpinning the conditions that MBCT/MBSR seek to address as well as enhancing outcomes by enabling these interventions to be better targeted at both universal and specific vulnerabilities. For this review, we assessed the quality of the appropriate studies based on Kazdin's (2007, 2009) recommended framework for enhancing methodological quality in this area.

There are several limitations of this review. First, we reviewed only randomised and non-randomised controlled studies. Other types of studies, such as observational and case studies, might produce more detailed data concerning the mechanisms of how and the reasons why MBCT/MBSR interventions can lead to change. A second limitation is that the main targeted population in this review comprised adults with diagnosed physical and/or psychological conditions. Focusing on other types of population, such as healthy people or children, might highlight different mechanisms underlying mindfulness interventions at different stages of the lifespan and with different profiles of universal and specific vulnerability. Thirdly, only published studies were included in this review

and so there might be some publication bias in the findings. Fourth, this review did not consider the fidelity of the MBCT and MBSR, nor how they were implemented by participants. We hypothesise that this would significantly influence the mechanisms and mediators being examined and is essential for future work to incorporate.

2.7 Recommendations

This review suggests that the field of testing mechanisms of mindfulness interventions might benefit from delineating universal and specific vulnerabilities in populations with physical and/or psychological conditions, so that we can better understand what any mindfulness-based intervention can change and what a mindfulness-based intervention adapted for particular populations specifically change.

The emerging theoretical framework for MBCT/MBSR draws on aspects of cognitive science (e.g., attention and executive control and decentering) and trans-diagnostic work (e.g., repetitive thought and experiential avoidance). This emerging model is being clarified and developed as empirical understanding is built. Future mechanisms studies should clearly articulate which aspect of this framework and which specific mechanisms they are investigating. The second point is that following the criteria suggested by Kazdin (2007, 2009) could assist researchers when conducting future studies aimed at identifying mechanisms of change in interventions. More recent developments in conceptual thinking and methodology can further enhance this field. Future research in this area might benefit from this focus on universal and specific mechanisms and triangulating experimental, neuroscience and self-report measures to test potential biological, psychological and social processes that might lead to a better understanding of how MBCT/MBSR interventions work in populations with physical and/or psychological conditions. Finally, researchers need to build in sufficient time

points in their study designs so as to be able to determine the shape and temporal sequencing of change.

Table 2.1
Inclusion/exclusion criteria of the review

	Inclusion criteria	Exclusion criteria
Types of trials	Randomised controlled trial and controlled trial aimed at examining mechanisms or mediators of change	Case-control trials, cohort trials, cross-sectional trials, case reports, series and qualitative trials
Types of publication	Published trials reported in any language	Non-published trials and dissertations
Types of participants	Adults, 18 years and older, diagnosed with a physical health condition and/or, diagnosed with any psychological problem	Children and healthy people
Types of interventions	Studies of MBCT as specified by Segal et al., (2002, 2013) and MBSR as outlined by Kabat-Zinn (1990, 2013)	Other mindfulness interventions and short duration MBCT or MBSR
Types of outcomes	Any	
Types of comparators	Any comparator. This might include inactive control such as treatment as usual (TAU) and waiting list or active group, such as antidepressants or other psychological interventions	

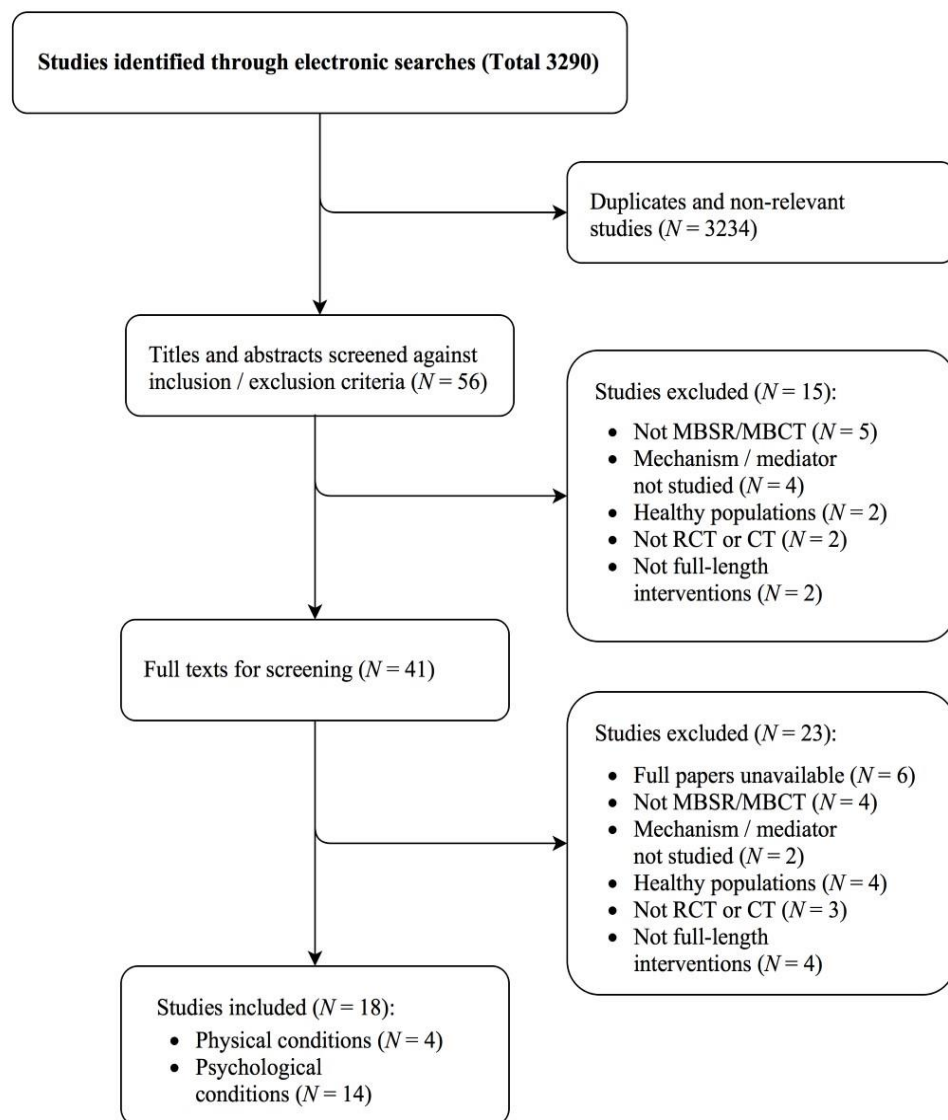


Figure 2.1. Flow of Studies Identification and Eligibility Determination

Table 2.2

Characteristics of studies with physical conditions populations

Author, year and country	Population	Inter-vention	Disorders	Study design	Comparator	Time-point assessments	Mediators studied (Assessment tool)	Statistical analysis used	Outcomes targeted	Outcome of Intervention	Findings in relation to 'mechanism of intervention'
Bränström et al., 2010 Sweden	N = 71 Male (n=1) and female (n=70) (Mean age 52 yrs.)	MBSR 8 weeks	Cancer	RCT	Adapted MBSR versus waitlist control	Two time-points (pre- and post-treatment)	• Mindfulness (Five-Facet Mindfulness Questionnaire/ FFMQ)	Baron & Kenny method	Psychological outcomes. -Primary (perceived stress) -Secondary (depressive symptoms, anxiety, posttraumatic avoidance symptoms and positive states)	• MBSR led to significant improvements in perceived stress, posttraumatic avoidance symptoms, positive states of mind and mindfulness compared to the control group.	• MBSR effects on perceived stress, posttraumatic avoidance symptoms and positive states of mind were mediated by increases in mindfulness skills.
Labelle et al., 2010 Canada	N = 77 Female (Mean age 53 yrs.)	MBSR 8 weeks	Cancer	CT	Adapted MBSR versus waitlist control	Two time-points (pre- and post-treatment)	• Mindfulness (Mindful Attention Awareness Scale (MAAS) • Rumination (Rumination-Reflection Questionnaire -Rumination Subscale/RRQ)	- Change scores - Baron & Kenny method - Nonparametric Bootstrapping (Preacher & Hayes method)	Psychological outcomes. -Primary (depressive symptoms)	•People in MBSR showed significant decreases in depressive symptoms and rumination and increases in mindfulness compared to the control group.	• MBSR effect on depression was mediated by a decrease in rumination • Significant changes in mindfulness did not show a mediating role.

Table 2.2 cont.

Characteristics of studies with physical conditions populations

Author, year and country	Population	Intervention	Disorders	Study design	Comparator	Time-point assessments	Mediators studied (Assessment tool)	Statistical analysis used	Outcomes targeted	Outcome of Intervention	Findings in relation to 'mechanism of intervention'
Labelle et al., 2015 Canada	N = 211 Male and female (Mean age 53 yrs.)	MBSR 8 weeks	cancer	CT	Adapted MBSR versus waitlist control	Three time-points (pre, mid and post treatment)	<ul style="list-style-type: none"> • Mindfulness (Mindful Attention Awareness Scale (MAAS) and Five-Facet Mindfulness Questionnaire (FFMQ)) • Rumination (Rumination-Reflection Questionnaire -Rumination Subscale/RRQ). • Worry (Penn State Worry Questionnaire/ PSWQ). 	Two-level hierarchical linear model (HLM)	Psychological outcomes. -Primary (stress symptoms and mood disturbance) -Secondary (mindfulness, rumination, worry and experiential avoidance)	•MBSR group showed a significant decrease in stress, mood disturbance, rumination, worry, experiential avoidance and increases in mindfulness skills.	<ul style="list-style-type: none"> • Decreases in rumination and worry (cancer-related worry) mediated the effects of MBSR on outcomes. • Changes in total of mindfulness measure did not mediate the effects of MBSR on outcomes.
O'Doherty et al. 2015 Ireland	N = 117 Male and female (Mean age 59 yrs.)	MBCT 8 weeks	Coronary heart disease (CHD) and current MDE	CT	MBCT versus waitlist control	Three time-points (pre, post and 6-month follow up)	<ul style="list-style-type: none"> • Mindfulness (Mindful Attention Awareness Scale/MAAS) 	Correlation analysis	Psychological outcomes. -Primary (current MDD in people with CHD) -Secondary (psychological adjustment and quality of life)	•MBCT group demonstrated significant improvements in depression, anxiety, psychological adjustment, mood, quality of life and mindfulness.	<ul style="list-style-type: none"> • The study found that significant associations between improvements in (depression, anxiety, psychological adjustment, quality of life and mood) and changes in mindfulness.

Table 2.3

Characteristics of studies with psychological conditions populations

Author, year and country	Population	Intervention	Disorders	Study design	Comparator	Time-point assessments	Mediators studied (Assessment tool)	Statistical analysis used	Outcomes targeted	Outcome of Intervention	Findings in relation to 'mechanism of intervention'
Batink et al. 2013 Netherlands	N = 130 Male and female (Mean age 44 yrs.)	MBCT 8 weeks	Current residual depressive symptoms after at least one episode of MDD	RCT	MBCT + TAU versus TAU alone	Two time-points (pre- and post-treatment)	<ul style="list-style-type: none"> • Mindfulness skills (Kentucky Inventory of Mindfulness/KIMS) •Worry (Penn State Worry Questionnaire/PSWQ) • Rumination (Rumination on Sadness Scale/RSS) •Positive affect (PA) and negative affect (NA) (experience sampling method-ESM) 	<ul style="list-style-type: none"> - Sobel-Goodman mediation analysis. - Multiple regression analysis 	Psychological outcomes. -Primary (residual depressive symptoms)	<ul style="list-style-type: none"> •MBCT group had significant decreases in depressive symptoms, worry and rumination and an increase in mindfulness skills. 	<ul style="list-style-type: none"> • Effects of MBCT on depressive symptoms were mediated by <ul style="list-style-type: none"> - An increase in a mindfulness skill (accept without judgment). - A decrease in worry. - An increase in positive affect. - A decrease in negative affect. • Rumination did not have a mediating role.
Bieling et al. 2012 Canada	N = 84 Male and female (Mean age 42-46 yrs.)	MBCT 8 weeks	Recurrent depression with current residual depressive symptoms	RCT	MBCT + medication taper versus maintenance antidepressants (m-ADM) versus placebo + medication taper	Three time-points (pre, post and 6-month follow up)	<ul style="list-style-type: none"> • Decentering (Toronto Mindfulness Scale/TMS) • Curiosity (Toronto Mindfulness Scale/TMS) •Wider Experiences (Experiences Questionnaire/EQ) •Rumination (Experiences Questionnaire/EQ⁹) 	<ul style="list-style-type: none"> -Multiple regression -Kraemer Method 	Psychological outcomes. -Primary (relapse rate and residual depressive symptoms)	<ul style="list-style-type: none"> • No differences between MBCT and m-ADM groups in terms of depression outcomes. 	<ul style="list-style-type: none"> •MBCT group showed increases in decentering, wider experiences and curiosity. •The increases in wider experiences and curiosity predicated depression at 6-month follow up. •Decentering and rumination did not have a mediating role.

⁹ The EQ measure was developed to measure "decentering" and "rumination", however, the authors in this study (Bieling et al., 2012) used it to refer to "wider experience" and "rumination".

Table 2.3 cont.

Characteristics of studies with psychological conditions populations

Author, year and country	Population	Intervention	Disorders	Study design	Comparator	Time-point assessments	Mediators studied (Assessment tool)	Statistical analysis used	Outcomes targeted	Outcome of Intervention	Findings in relation to 'mechanism of intervention'
Britton et al. 2012 USA	N = 52 Male and female (Mean age 48 yrs.)	MBCT 8 weeks	Recurrent depression with residual depressive symptoms	RCT	MBCT versus waitlist control	Two time-points (pre- and post-treatment)	• Emotional reactivity to social stress (laboratory-based stress induction + Spielberger state anxiety measure/STAI-YI)	Preacher and Hayes approach	Psychological outcomes. -Primary (residual depressive symptoms).	• MBCT led to significant decreases in depression and emotional reactivity.	• Significant decreases in emotional reactivity mediated the effects of MBCT on depression.
Geschwind et al. 2011 Netherlands	N = 130 Male and female (Mean age 44 yrs.)	MBCT 8 weeks	Current residual depressive symptoms after at least one episode of MDD	RCT	MBCT versus waitlist control	Two time-points (pre- and post-treatment).	• Activity pleasantness (Experience Sampling Method-ESM) • Positive affect (ESM) • Negative affect (ESM) • Reward experience.	Correlation analysis	Psychological outcomes. -Primary (residual depressive symptoms).	• MBCT group showed significant improvements in depressive symptoms, affect, activity pleasantness and reward, worry and rumination.	• Significant decreases in depression were associated with increases in: - Positive affect. - Activity pleasantness. - Reward experience.

Table 2.3 cont.

Characteristics of studies with psychological conditions populations

Author, year and country	Population	Intervention	Disorders	Study design	Comparator	Time-point assessments	Mediators studied (Assessment tool)	Statistical analysis used	Outcomes targeted	Outcome of Intervention	Findings in relation to 'mechanism of intervention'
Goldin et al. 2012 USA	N = 56 Male and female (Mean age 32 yrs.)	MBSR 8 weeks	Social Anxiety Disorder	RCT	MBSR versus Active control (Aerobic exercise/AE)	Two time-points (pre- and post-treatment)	• Self-referential brain network (Self-Referential Encoding Task) + fMRI	Multiple regression	Psychological outcomes. -Primary (social anxiety symptoms)	•MBSR group showed an increase in positive self-views and decrease in negative self-views when compared to a AE group.	• Significant changes in self-views as well as dorsomedial pre- frontal cortex (DMPFC) activity during negative self-view were associated with significant reductions in social anxiety in the MBSR group.
Hoge et al. 2015 USA	N = 38 Male and female (Mean age 38 yrs.)	MBSR 8 weeks	Generalised Anxiety Disorder	RCT	Adapted - MBSR versus active control (stress management education/SME)	Two time-points (pre- and post-treatment)	• Mindfulness (Five-Facet Mindfulness Questionnaire/FMQ) • Decentering (Experience Questionnaire /EQ)	Multiple mediation model and Preacher and Hayes approach (bootstrapping)	Psychological outcomes. -Primary (generalised anxiety symptoms)	•MBSR group had a significant decrease in generalised anxiety.	• Effect of MBSR on anxiety was mediated by an increase in decentering. • Effect of MBSR on worry was mediated by increases in mindfulness (awareness and non-reactivity).
Holzel et al. 2013 USA	N = 29 Male and female (Mean age 36 yrs.)	MBSR 8 weeks	Generalised Anxiety Disorder	RCT	Adapted-MBSR versus active control (stress management education: SME)	Two time-points (pre- and post-treatment)	• Brain activation and connectivity (fMRI)	Multiple regression	Psychological outcomes. -Primary (generalised anxiety symptoms)	• People in MBSR showed changes in ventrolateral prefrontal regions (VLPFC) activation and amygdala–prefrontal connectivity.	• The changes in ventrolateral prefrontal regions (VLPFC) activation and amygdala–prefrontal connectivity were associated with improvements in generalised anxiety disorder.

Table 2.3 cont.

Characteristics of studies with psychological conditions populations

Author, year and country	Population	Inter-vention	Disorders	Study design	Comparator	Time-point assessments	Mediators studied (Assessment tool)	Statistical analysis used	Outcomes targeted	Outcome of Intervention	Findings in relation to 'mechanism of intervention'
Jermann et al. 2013 Switzerland	N = 60 Male and female (Mean age 45 yrs.)	MBCT 8 weeks	Recurrent depression 3 groups (Remitted people, depressed group and non-depressed group)	RCT	MBCT +TAU versus TAU	Three time-points (pre, post and 9 month follow up) for only MBCT group. One assessment for depressed and non-depressed groups.	<ul style="list-style-type: none"> • Cognitive functioning: <ul style="list-style-type: none"> - Autobiographical memory (Autobiographical Memory Test/AMT) - Shifting abilities (PM task) - Dysfunctional attitude (Dysfunctional Attitude Scale/DAS) - Mindful Attention (Mindfulness Attention Awareness Scale/MAAS) - Rumination (Rumination/Reflection Questionnaire/RRQ) 	Correlation analysis	Psychological outcomes. Cognitive functioning.	•MBCT group showed significant decrease in depressive symptoms, and dysfunctional attitude.	MBCT group showed a significant decrease in dysfunctional attitudes at 9 months follow up.
Kearns et al. 2015 Australia	N = 203 Male and female (Mean age 48 yrs.)	MBCT 8 weeks	Recurrent depression	RCT	MBCT + DRAM versus depression relapse active monitoring (DRAM).	Three time-points (pre, post and 2 years' follow-up)	<ul style="list-style-type: none"> •Rumination (Rumination Response Style Questionnaire/RRS). •Mindfulness (Five-Facet Mindfulness Questionnaire/FFMQ). 	-Regression -Non-parametric Bootstrapping	Psychological outcomes. -Primary (relapse rate)	•MBCT group showed significant reductions in relapse rate.	<ul style="list-style-type: none"> • MBCT effects on depressive relapse were mediated by significant increases in mindfulness. • Rumination did not mediate the relationship between MBCT and relapse.

Table 2.3 cont.

Characteristics of studies with psychological conditions populations

Author, year and country	Population	Inter-vention	Disorders	Study design	Comparator	Time-point assessments	Mediators studied (Assessment tool)	Statistical analysis used	Outcomes targeted	Outcome of Intervention	Findings in relation to 'mechanism of intervention'
Kuyken et al. 2010 UK	N = 123 Male and female (Mean age 49 yrs.)	MBCT 8 weeks	Recurrent depression with residual depressive symptoms	RCT	MBCT+ discontinuation of antidepressants (ADM) versus maintenance antidepressants (m-ADM)	Three time-points (pre, post and 15 month follow up)	<ul style="list-style-type: none"> • Mindfulness skill (Kentucky Inventory of Mindfulness/KI MS) • Self-compassion (Self-Compassion Scale/SCS) • Cognitive reactivity (laboratory task + Dysfunctional Attitude Scale/DAS). 	Mediation and moderation analytic framework (Kraemer method)	Psychological outcomes. -Primary (relapse rate and residual depressive symptoms).	<ul style="list-style-type: none"> • The effects of MBCT were similar to m-ADM in terms of relapse and residual depressive symptoms. 	<ul style="list-style-type: none"> • MBCT's effects were mediated by significant increases in: -Mindfulness -Self-compassion. • High reactivity predicted a worse outcome for m-ADM group, but this relationship did not show up in MBCT group.
Shahar et al. 2010 USA	N = 52 Male and female (Mean age 47 yrs.)	MBCT 8 weeks	Recurrent depression with residual depressive symptoms	RCT	MBCT versus waitlist control	Two time-points (pre- and post-treatment)	<ul style="list-style-type: none"> • Brooding (Rumination Response Scale/RRS) • Reflective pondering (Rumination Response Scale/RRS) • Mindfulness (The Mindful Attention Awareness Scale/MAAS) 	Preacher and Hayes approach	Psychological outcomes. -Primary (residual depressive symptoms).	<ul style="list-style-type: none"> • People in MBCT group reported significant decreases in depression compared to waitlist group. 	<ul style="list-style-type: none"> • The relationship between MBCT and depression was mediated by -increases in mindfulness. -decreases in brooding. • Reflective pondering did not play a role in the mediation.

Table 2.3 cont.

Characteristics of studies with psychological conditions populations

Author, year and country	Population	Intervention	Disorders	Study design	Comparator	Time-point assessments	Mediators studied (Assessment tool)	Statistical analysis used	Outcomes targeted	Outcome of Intervention	Findings in relation to 'mechanism of intervention'
Van Aalderen et al. 2012 Netherlands	N = 219 Male and female (Mean age 48 yrs.)	MBCT 8 weeks	Current or recurrent depression	RCT	MBCT + TAU versus TAU alone	Two time-points (pre- and post-treatment).	<ul style="list-style-type: none"> •Rumination (Rumination on Sadness Scale/RSS) •Worry (Penn State Worry Questionnaire/P SWQ) •Mindfulness skills (Kentucky Inventory of Mindfulness/KI MS). 	Multivariate model. Bootstrapping.	Psychological outcomes. -Primary (residual depressive symptoms or current depressive symptoms).	<ul style="list-style-type: none"> •MBCT group showed significant decreases in depressive symptoms, worry and rumination and an increase in mindfulness skill. 	<ul style="list-style-type: none"> •The relationship between MBCT and depression was mediated by -A decrease in rumination; -A decrease in worry; - An increase in a mindfulness skill (accept without judgment).
Van den Hurk et al. 2012 Netherlands	N=71 Male and female (Mean age 49 yrs.)	MBCT 8 weeks	Recurrent depression	RCT	MBCT + TAU versus TAU alone	Two time-points (pre- and post-treatment)	<ul style="list-style-type: none"> •Attentional processing (Attentional Network Test). 	Correlation analysis	Psychological outcomes. -Primary (residual depressive symptoms or current depressive symptoms).	<ul style="list-style-type: none"> •MBCT led to reductions in depressive symptoms and rumination and increases in mindfulness when compared to TAU. • No significant differences between MBCT and TAU in components of attention 	<ul style="list-style-type: none"> •Attentional processing did not mediate the relationship between MBCT and depression.
Vøllestad et al. 2011 Norway	N=76 Males and female (Mean age 43 yrs.)	MBSR 8 weeks	Anxiety disorders	RCT	MBSR versus waitlist control	Two time-points (pre- and post-treatment) 6-month follow up for MBSR group only	<ul style="list-style-type: none"> •Mindfulness (Five-Facet Mindfulness Questionnaire/F FMQ) 	-Baron & Kenny method -Non-parametric Bootstrapping (Preacher & Hayes)	Psychological outcomes. -Primary (acute anxiety symptoms). -Secondary (worry and trait anxiety).	<ul style="list-style-type: none"> •MBSR group showed significant decreases in anxiety, depression and worry and an increase in mindfulness. 	<ul style="list-style-type: none"> •Effects of MBSR on acute anxiety, worry and trait anxiety, but not depression were mediated by increases in mindfulness.

Table 2.4

Risk bias in studies with physical conditions

Study	Random sequence generation	Allocation concealment	Blinding of participants	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Eligibility criteria specified	Power calculation	Compliance with interventions	Data collection tools valid	All participants accounted for
Bränström et al. 2010	Low	Unclear	High	High	Low	Low	Yes	Yes	Unclear	Yes	Yes
Labelle et al. 2010	High	High	High	High	Low	Low	Yes	Unclear	Yes	Yes	Yes
Labelle et al. 2015	High	High	High	High	Low	Low	Yes	Unclear	Unclear	Yes	Yes
O'Doherty et al. 2015	High	High	High	High	Low	Low	Yes	Yes	Yes	Yes	Yes

Table 2.5

Risk bias in studies with psychological conditions

Study	Random sequence generation	Allocation concealment	Blinding of participants	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Eligibility criteria specified	Power calculation	Compliance with interventions	Data collection tools valid	All participants accounted for
Batink et al. 2013	Low	Low	High	Unclear	Low	Low	Yes	Yes	Yes	Yes	Yes
Bieling et al. 2012	Low	Low	High	Low	Low	Low	Yes	Unclear	Yes	Yes	Yes
Britton et al. 2012	Low	Low	High	Low	Low	Low	Yes	Yes	Yes	Yes	Yes
Geschwind et al. 2011	Low	Low	High	Low	Low	Low	Yes	Yes	Yes	Yes	Yes
Goldin et al. 2012	Low	Unclear	High	High	Low	Low	Yes	Yes	Unclear	Yes	Yes
Hoge et al. 2015	Low	Low	High	Low	Low	Low	Yes	Unclear	Yes	Yes	Yes
Hölzel et al. 2013	Low	Low	High	Low	Low	Low	Yes	Unclear	Yes	Yes	Yes
Jermann et al. 2013	Low	Low	High	Low	Low	Low	Yes	Yes	Yes	Yes	Yes
Kearns et al. 2015	Low	Low	High	Low	Low	Low	Yes	Yes	Yes	Yes	Yes
Kuyken et al. 2010	Low	Low	High	Low	Low	Low	Yes	Yes	Yes	Yes	Yes
Shahar et al. 2010	Low	Low	High	High	Low	Low	Yes	Yes	Unclear	Yes	Yes
Van Aalderen et al. 2012	Low	Low	High	Unclear	Low	Low	Yes	Yes	Yes	Yes	Yes
Van den Hurk et al. 2012	Low	Low	High	Unclear	Low	Low	Yes	Yes	Yes	Yes	Yes
Vøllestad et al. 2011	Unclear	Unclear	High	High	Low	Low	Yes	Unclear	Yes	Yes	Yes

Table 2.6

Evaluation of studies with physical conditions populations based on the review framework

Study name	1. Did the study use a theory?	2. Did the study use measures to assess the mediators?	3. Did the study use measures that can reflect different perspectives?	4. Did changes in processes are specifically targeted by MBCT/MBSR?	5. Did changes in potential mediators occur during the MBCT/MBSR?	6. Did changes in mediators precede changes in outcomes?	7. Did the study use enough time-point assessments?	8. Did the study use an appropriate statistical analysis?	Total of scores
Bränström et al. 2010	1	1	0	1	1	0	0	1	5
Labelle et al. 2010	1	1	0	1	1	0	0	1	5
Labelle et al. 2015	1	1	0	1	1	1	1	1	7
O'Doherty et al. 2015	1	1	0	1	1	1	1	0	6

Note. 1= Yes, 0=No

Table 2.7

Evaluation of studies with psychological conditions populations based on the review framework

Study name	1. Did the study use a theory?	2. Did the study use measures to assess the mediators?	3. Did the study use measures that can reflect different perspectives?	4. Did changes in processes are specifically targeted by MBCT/MBSR?	5. Did changes in potential mediators occur during the MBCT/MBSR?	6. Did changes in mediators precede changes in outcomes?	7. Did the study use enough time-point assessments?	8. Did the study use an appropriate statistical analysis?	Total of scores
Batink et al 2013	1	1	0	1	1	0	0	1	5
Bieling et al. 2012	1	1	0	1	1	1	1	1	7
Britton et al. 2012	1	1	1	1	1	0	0	1	6
Geschwind et al. 2011	1	1	0	1	1	0	0	0	4
Goldin et al. 2012	1	1	1	1	1	0	0	1	6
Hoge et al. 2015	1	1	0	1	1	0	0	1	5
Hölzel et al. 2013	1	1	1	1	1	0	0	1	6
Jermann et al. 2013	1	1	1	1	1	0	0	0	5
Kearns et al. 2015	1	1	0	1	1	1	1	1	7
Kuyken et al. 2010	1	1	1	1	1	1	1	1	8
Shahar et al. 2010	1	1	0	1	1	0	0	1	5
Van Aalderen et al. 2012	1	1	0	1	1	0	0	1	5
Van den Hurk et al. 2012	1	1	1	1	1	0	0	0	5
Vøllestad et al. 2011	1	1	0	1	1	0	0	1	5

Note. 1= Yes, 0=No

Chapter 3.0

Study 2

Exploring the Impact of Mindfulness-Based Cognitive Therapy (MBCT) on Physical Health Symptoms: A Secondary Analysis of the PREVENT Randomised Controlled Trial

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3.1 Abstract

Background: Somatic symptoms co-occurring with physical health conditions are highly prevalent in depression, being associated with increased morbidity, greater health care use, poor medical outcomes, greater severity and duration of depression as well as decreased quality of life. Consequently, it has been suggested that if treatments can more effectively target these somatic symptoms and physical health comorbidities, then the depression outcomes could be improved, and the health burden of depression might be decreased. Mindfulness-Based Cognitive Therapy (MBCT) as a body-mind treatment has shown positive effects in decreasing relapse rates and residual depressive symptoms. However, its effects on somatic symptoms or physical health comorbidity have yet to be established. Consequently, the aim of this secondary analysis is to explore the impact of MBCT on somatic and physical health symptoms. **Methods:** A secondary analysis of the PREVENT randomised controlled trial comparing MBCT to antidepressants (ADM) was conducted, focusing on changes in the Medical Symptoms Checklist (MSCL) as a measure of somatic and physical health symptoms as well as whether baseline MSCL levels moderate depression outcomes. **Results:** The findings of exploratory factor analysis showed the MSCL measure loaded onto two factors (physical and psychological). There was no significant difference between MBCT and ADM conditions at 12 and 24 months in the extent to which they reduced either physical or psychological symptoms on the MSCL. Baseline MSCL physical symptoms moderated treatment response, such that those with higher levels of symptoms did better in MBCT relative to m-ADM in terms of greater residual depression symptom relief and lower depression relapse rates. **Conclusions:** Baseline MSCL physical symptoms showed a moderation role for the effects of MBCT vs. m-ADM on relapse rates and residual

depressive symptoms. This result could help with understanding for whom MBCT may be suited.

Keywords: MBCT, depression, medical symptoms, secondary analysis.

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Conflict of interest

WK is Director of the Oxford Mindfulness Centre and until 2015 was an unpaid Director of the Mindfulness Network Community Interest Company. He is the Principal Investigator of several externally funded projects evaluating the efficacy of MBCT. The other authors declare that they have no conflict interest.

Authors' contributions

MA drafted the analysis protocol, analysed the data and drafted the manuscript. BD checked the statistical analysis plan, checked the analyses and reviewed the manuscript. WK participated in the design of the analysis protocol, checked the analyses and commented on the manuscript. OU checked the analyses and reviewed the manuscript. All authors read and approved the final manuscript.

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3.2 Background

The somatic symptoms of depression are defined as “various bodily sensations that an individual with depression perceives as unpleasant or worrisome” (Kapfhammer, 2006, p. 229). According to the Diagnostic and Statistical Manual of Mental Disorders-fifth edition (DSM-5), three out of the nine symptoms of a major depressive disorder are of a somatic nature, including insomnia or hypersomnia, fatigue/ loss of energy, and change in appetite (DSM-5, 2013, p. 161). Other common somatic symptoms include headache, constipation, weakness, general aches and pains and backache. These symptoms are highly prevalent, with almost two thirds of individuals with major depressive disorder reporting them (Tylee & Gandhi, 2005). These somatic symptoms are often underdiagnosed and undertreated (Tylee & Gandhi, 2005) and frequently co-occur with significant physical health comorbidity in depression (the presence of medical conditions or symptoms alongside depression). Such comorbidity is very common in depression (Katon, 2003, 2011; Kisely et al., 2005; Moussavi et al., 2007; Naylor et al., 2012), with rates of physical health problems being elevated in people with it compared to those without (Katon, Lin, & Kroenke, 2007).

Both somatic symptoms of depression and medical comorbidity have been found to be associated with increased morbidity, health care use, suicide as well as poor medical outcomes and decreased quality of life (Barsky, Orav, & Bates, 2005; Blair, Robinson, Katon, & Kroenke, 2003; Chisholm et al., 2003; Fortin et al., 2006; Katon, 2011; Kisely et al., 2005; Moussavi et al., 2007; Sareen. et al., 2006). Importantly, they often lead to increases in the severity and duration of depression as well as increased risk of subsequent relapse (Jeong et al., 2014; Ohayon, Schatzberg, & Ohayon Mm, 2003; Richards, 2011; Trivedi, 2004). Regarding which, Iosifescu et al. (2003) found that higher medical comorbidity is associated with a poorer response to antidepressants and

lower remission rates. Hence, depression outcomes may be improved, if treatments can more effectively target these somatic symptoms and physical health comorbidities. This might also help promote a full recovery and decrease the health burden of depression (Trivedi, 2004).

Mindfulness-based cognitive therapy (MBCT) has been designed as a prevention programme for helping people who are at high risk of recurrent depression (Segal, Williams & Teasdale, 2002, 2013). A range of evidence currently suggests that such therapy is comparably effective as maintenance anti-depressant medication in preventing depressive relapse (Kuyken et al., 2015; Segal, Martin & Joseph, 2010). There is also emerging evidence that MBCT is effective at treating residual depression symptoms in those only partially in recovery and in treating acute depression (Barnhofer et al., 2009; Eisendrath et al., 2016; van Aalderen et al., 2012). However, whether MBCT can repair somatic/physical health symptoms or medical morbidity remains an open question.

There are reasons to hypothesise that mindfulness may be helpful in ameliorating somatic/physical health symptoms. A key component of MBCT involves helping individuals train a style of attention where they focus on bodily sensations in a non-judgmental way (Crane et al., 2017). This may in part act by modulating interoceptive awareness (Craig, 2002), defined as the “the ability to detect changes in the body (including muscles, skin, joints and viscera), enabling individuals to experience bodily ‘feelings’ such as pain, temperature” (Dunn et al., 2010, p. 1133). People with depression have been found to show reduced interoceptive awareness (Dunn et al., 2010; Dunn, Dalgleish, Ogilvie, & Lawrence, 2007) and there is a growing awareness of the wide-ranging effects of modulating such awareness via mindfulness practice on a range of cognitive, affective and physical health outcomes (Farb et al., 2015).

If MBCT is better able to treat the somatic symptoms of depression than other approaches, it means that it should be differentially effective in repairing depression in those individuals who present at baseline with elevated levels of somatic symptoms and physical health comorbidities. In other words, the presence of these symptoms should moderate both acute treatment outcomes and long-term rates of recovery. Moderators pertain to variables that can be assessed prior the initiation of an intervention, which need to be correlated with the outcome and intervention statistically, being able to explain the relationship between the intervention and the outcomes (Johansson & Høglend, 2007; Murphy, Cooper, Hollon & Fairburn, 2009).

Accordingly, the present study was aimed at testing whether MBCT is effective in modulating somatic/physical health symptoms and whether the presence of somatic/physical health symptoms at baseline moderates the response to MBCT. To this end, a secondary analysis of the PREVENT trial (Kuyken et al., 2016) was conducted. This study examined the effects of MBCT with tapering versus maintenance antidepressants (m-ADM) in preventing depression relapse in people with a history of recurrent depression and found that both were effective at reducing relapse rates at two years. The PREVENT trial also included the Medical Symptoms Checklist (MSCL; Travis, 1977), which measures a wide range of medical symptoms. Kuyken et al. (2016) reported that there was no difference between the two groups in change in the total MSCL score from baseline to 12 or 24 months follow up. However, close inspection of the MSCL reveals that it involves a mixture of items considering physical health/somatic symptoms and items measuring general psychological distress. The psychometric properties of the MSCL have never been robustly examined and it is possible that a two-factor solution will emerge, measuring these physical and psychological items. Consequently, the present study will involve, first, factor analysing the MSCL and then

examining whether MBCT differentially repairs physical symptoms factor on the MSCL relative to m-ADM. Second, it will examine if baseline scores on the MSCL physical symptom factors predict a superior response to MBCT relative to m-ADM.

3.3 Method

3.3.1 Summary of the PREVENT Trial

Participants were recruited through GPs and advertisements in four areas of the south west of the UK (Exeter and East Devon, North and mid-Devon, South Devon, and Bristol). Eligible participants were adults 18 and older who: had a diagnosis of recurrent major depressive disorder (either in full or partial remission); had suffered three or more previous major depressive episodes; and who were on maintenance antidepressant medication in line with the British National Formulary (BNF) and NICE guidance. Randomisation was conducted based on a computer-generated random number sequence. The stratification variables were the recruitment site (Exeter and East Devon, North and mid-Devon, South Devon and Bristol) and severity of depression (asymptomatic vs. partially symptomatic at intake). Participants were randomised into MBCT or maintenance antidepressant (m-ADM) groups. MBCT is a programme outlined by Segal et al. (2002, 2013) and developed based on Mindfulness-Based Stress Reduction (MBSR). It comprises an individual orientation session and eight weekly 2.5-hour group sessions, which involve mindfulness meditation exercises and certain cognitive therapy techniques. This course was designed to help people become aware of problematic styles of thinking and reacting, decentre from these and to respond more adaptively at times of potential depressive relapse. The primary outcome of PREVENT was time to depressive relapse rate up to two years, which was assessed based on Longitudinal Interval Follow-up Evaluation, a form of the Structured Clinical Interview for DSM-IV (SCID). The secondary outcomes were residual depressive symptoms assessed by two measures: the

GRID-Hamilton Rating Scale for Depression (GRID-HAMD) and the Beck Depression Inventory (BDI-II). One of strengths of PREVENT regarding assessing acute depression outcomes is that the researchers used both people's reported subjective outcomes and clinician assessed objective one (for detailed procedures, see Kuyken et al. (2010, 2016)). Of particular relevance to the current study, physical health/somatic symptoms were assessed as an additional secondary outcome using the Medical Symptoms Checklist (MSCL; Travis, 1977).

3.3.2 Measures used in the Analysis

3.3.2.1 The Medical Symptoms Checklist (MSCL).

The Medical Symptoms Checklist (MSCL) was developed by John Travis in 1977 (Travis, 1977) and is a self-reported measure of 109 medical symptoms. Ninety-five items apply to both males and females, including headache, loss of balance, dizzy spells, shortness of breath with normal activity, itching or burning skin, and pain in abdomen, worrying lot, lonely or depressed as well as nervousness or anxiety. Three items apply to males only, such as painful testicles and 11 items apply to females only, such as menstrual problems and painful breasts. Participants are asked if they have had these symptoms over the last month, with the responses being Yes or No. The total score is the total number of symptoms endorsed, with a minimum of 0 and the maximum being 98 for males and 106 for females. The MSCL has been used frequently in the mindfulness literature to index physical health outcomes (e.g., Carmody & Baer, 2008; Kabat-Zinn, 1982; Kabat-Zinn, Lipworth, & Burney, 1985; Kuyken et al., 2016), but its psychometric properties have yet to be established. Consequently, in the present study the aim was to establish its validity and reliability and then moved on to test the core hypotheses.

3.3.2.2 The Beck Depression Inventory (BDI-II).

The Beck Depression Inventory (BDI-II; Beck & Steer, Brown, 1996) is a 21-item self-report measure of depression severity, with each item being rated from 0 to 3, giving a minimum score of 0 and a maximum of 63. The BDI-II assesses psychological, cognitive and physical symptoms of depression, including hopelessness, guilt feelings, fatigue, sense of failure, self-dissatisfaction, suicidal ideas, crying, irritability, social withdrawal, body image, work difficulties, insomnia as well as appetite and weight loss. This measure has been widely used with different populations. The BDI-II has showed good psychometric properties with Cronbach's Alpha (0.94) in the UK (Cameron et al., 2011).

3.3.2.3 The GRID-Hamilton Depression Rating Scale (GRID-HAMD).

The GRID-Hamilton Depression Rating Scale (GRID-HAMD; Williams, 1998) is an interview to assess depression severity, which is administered by a health care professional. It contains 21 items covering the core symptoms of depression, each of which is rated from 0 (absent) to 3 (severe). The first 17 items measure the severity of core depressive symptoms and the remaining four assess additional symptoms sometimes related to depression (including paranoia, obsessional and compulsive symptoms). The GRID-HAMD is scored based on the first 17 items only, identifying four categories: not depressed (0–7), mild depression (8–16), moderate depression (17–23) and severe depression (24–51).

3.3.3 Statistical Analyses

Data analysis was performed based on the Intent-To-Treat (ITT) sample that considers all randomised participants using SPSS 23.0. The analysis protocol was outlined before accessing the data. To establish the psychometric properties of the MSCL, exploratory factor analysis and Cronbach's alpha were used focusing only on

items pertaining to both genders. To examine how well MBCT performed versus m-ADM repair physical health symptoms, analysis of covariance (ANCOVA) was used to examine effects of the two on medical symptoms based on the total MSCL measure at 12 and 24 months, controlling for baseline MSCL severity and the PREVENT trial stratification variables (recruitment site and severity of depression at randomisation). The recruitment site was dummy coded, while the severity of depression at randomisation, as a binary stratification, was entered as 0 and 1. Cox's regression was used to assess whether baseline total MSCL moderates the relapse rates outcomes in MBCT vs. m-ADM at 12 and 24 months. Also, a linear regression was used to assess whether baseline MSCL moderates residual depressive symptoms, as assessed by BDI and GRID-HAMD in MBCT vs. m-ADM at post intervention, 9 months and 12 months. The Kraemer moderation approach (Kraemer et al., 2002) was followed, additionally adjusting for PREVENT trial stratification variables. Consequently, at Step One, the recruitment site, severity of depression for the randomisation group (MBCT vs. m-ADM) and the moderator (baseline MSCL, measures before the intervention) were entered. At Step Two, the interaction between group and the moderator was entered. Moderation was indicated by a significant increase in model fit from Step One to Step Two and if a significant moderation were found, the Hayes method of simple slopes would be used to resolve the interaction (Hayes, 2012).

3.4 Results

3.4.1 Sample Characteristics

A total of 424 people was recruited through 95 GPs at four sites: Exeter, North Devon, South Devon and Bristol. Of the 424 people, 24 % were male and 76 % female with a mean age of 49 and ranging from 20 to 79 years of age. Approximately 99 % were of White British ethnic origin and 48 % were married. There were no significant

differences between the two groups for all the demographic data, except for gender. Descriptive statistics of the MSCL and the number of people who completed it at baseline, 12 months and 24 months for the MBCT and m-ADM groups are shown in Table 3.1.

3.4.2 Psychometrics Characteristics of the MSCL Measure Results

3.4.2.1 Exploratory factor analysis (EFA).

Exploratory factor analysis (EFA) was carried out on 95 out of the 109 items of the MSCL measure¹⁰ and to ascertain whether the data were suitable for factor analysis, all 424 valid cases were included in the initial screening. Prior to analysis, the suitability of EFA was assessed through two tests: Kaiser-Meyer-Olkin (KMO)¹¹ and Bartlett's test of sphericity¹². The findings showed that the overall Kaiser-Meyer-Olkin (KMO) measure was 0.80, with a classification of 'adequate', according to Kaiser (1974), whilst Bartlett's test was highly significant ($\chi^2 = 11530.38, p < 0.000$), thus indicating that EFA was appropriate.

Initial EFA revealed 32 components (their eigenvalues were smaller than one), which explained approximately 49.5 % of the total variance. However, visual inspection of the scree plot indicated that only two of these components should be retained (a line clearly flattened out after two factors) (Cattell, 1966). The two-component solution explained 15.5 % of the total variance. These two factors were named physical and psychological according to the nature of each factor's symptoms. Initially, a range of rotation methods (e.g., varimax, promax and direct oblimin) was examined, where only small differences were found in the solutions reached. Eventually, the decision was made to focus on a direct oblimin rotation, because it assumes that all the factors are correlated

¹⁰ 14 items specific to gender (for males or females only) were excluded.

¹¹ This test assesses whether factors are available or not.

¹² This test assesses the overall significance of all the correlations within the correlation matrix.

(the component correlation matrix for the two factors was larger than 0.32). However, only the items that loaded most strongly (loadings < 0.40) onto separate factors were kept. The component loadings of the rotated solution are presented in Table 3.2.

3.4.2.2 Reliability of the MSCL.

The reliability of the total MSCL and the two factors were good. Cronbach's alpha for the total MSCL was (0.93), for the physical component was (0.83) and for the psychological component was (0.85). Moreover, the correlation between the two factors was relatively high $r = .42$, $p < .01$.

3.4.3 Aim One: Evaluating the Extent to which MBCT vs. m-ADM Alleviates

Medical Symptoms

The means and standard error (SEM) for the total MSCL as well as the MSCL factors (physical and psychological) at 12 months and 24 months are presented in Figures 3.1, 3.2 and 3.3. An ANCOVA (adjusting for baseline severity and the stratification variables) found that the MBCT and m-ADM groups did not differ significantly in their medical symptoms at 12 months or 24 months in terms of the MSCL total score, $F_s < 1$. Similar analyses were repeated based on the two factors of the MSCL (physical and psychological). The findings show that there were no differences between the MBCT and m-ADM groups in either factor at 12 months or 24 months, $F_s < 1$.

3.4.4 Aim Two: Evaluating Whether Baseline Medical Symptoms Moderate the Relationship Between MBCT When Compared to m-ADM and Depression

Outcomes

3.4.4.1 Moderation analysis for depression relapse rates.

The results indicated that baseline medical symptoms (the total MSCL) moderate the effects of MBCT vs. m-ADM on the hazard of relapse at 12 and 24 months. At 12 months, the main effect of the total MSCL at Step One was significant (Wald = 10.73, $p < .001$, hazard ratio = 1.02) and there was also a significant interaction between the total MSCL and group at Step Two (Wald = 10.93, $p < .001$, hazard ratio = 1.03) (see Figures 3.4 and 3.5). At 24 months, the main effect of the total MSCL (Wald = 9.64, $p < .002$, hazard ratio = 1.02) and the interaction between the total MSCL and group (Wald = 8.91, $p < .003$, hazard ratio = 1.03) were also significant (see Figures 3.6 and 3.7). This means that high MSCL symptoms at baseline predicted worse 12 and 24-month survival rates. This effect was driven by the m-ADM group, in that higher MSCL symptoms predicted higher relapse rates in this group, but not in the MBCT group.

A similar pattern emerged when looking at the physical and psychological factors at both 12 and 24 months. At 12 months, the main effects and interactions were significant for both the physical factor (main effect, Wald = 5.27, $p < .02$, hazard ratio=1.10; interaction, Wald = 6.00, $p < .01$, hazard ratio = 1.11) and the psychological factor (main effect, Wald = 6.22, $p < .01$, hazard ratio = 1.10, interaction, Wald = 6.46, $p < .01$, hazard ratio = 1.12). At 24 months, the main effect and interaction were significant for the physical factor (main effect, Wald = 3.29, $p < .07$, hazard ratio = 1.03; interaction, Wald = 5.76, $p < .02$, hazard ratio = 1.10) and the psychological factor (main effect, Wald = 4.21, $p < .04$, hazard ratio = 1.04; interaction, Wald = 4.67, $p < .03$, hazard ratio = 1.10). This means that high MSCL physical and psychological symptoms

at baseline predict worse 12 and 24-month survival rates. This effect was driven by the m-ADM group, in that higher MSCL physical and psychological symptoms predicted higher relapse rates in this group, but not in the MBCT one.

3.4.4.2 Moderation analysis for residual depressive symptoms.

3.4.4.2.1 BDI results. At post-intervention, Step One of the overall model was significant, $F = 22.37$, $p < .001$, and accounted for (30 %) of the variance in residual depressive symptoms. However, when adding the interaction term at Step Two, the model did not significantly improve (F change = 0.76, $p = .38$). Similarly, at 9 months, Step One of the overall model was significant ($F = 10.1$, $p < .000$) and accounted for (18 %) of the variance in the outcome. However, after adding the interaction term in Step Two, the model did not improve (F change = 2.41, $p = .12$).

At 12 months, the overall model one was significant ($F = 14.48$, $p < .000$) and accounted for 23 % of the variance in the outcome. When adding the interaction term at Step Two, the model improved significantly (F change = 3.73, $p < .054$, $B = 0.14$, $Beta = 0.13$, $t = 1.93$) (see Table 3.3). To resolve this interaction, depression symptoms were plotted as a function of the MSCL for each condition separately, thus showing that high MSCL symptoms at baseline predicted worse 12-months residual depressive symptoms. This effect was driven by the m-ADM group, in that higher MSCL symptoms predicted higher residual depressive symptoms in this group, but not in the MBCT one (see Figure 3.8).

The same analyses were repeated based on the two factors of the MSCL (physical and psychological). The physical symptoms moderated the effects of MBCT vs. m-ADM groups on residual depressive symptoms at 9 months (see Figure 3.9) and were marginally significant at 12 months (See Table 3.4). Regarding the psychological component, no moderation effects were found at both of the follow-ups (see Table 3.5).

3.4.4.2.2 GRID-HAMD results. Table 3.3 shows that baseline MSCL moderated the relationship between MBCT vs. m-ADM and residual depressive symptoms, as assessed by GRID-HAMD at 9 months, but not at post-intervention and 12 months. At 9 months, the overall model one was significant ($F = 8.43, p < .000$) and accounted for (13 %) of the variance in the outcome. When adding the interaction term at Step Two, the model improved significantly (F change = 6.58, $p < .01$, $B = 0.11$, Beta= 0.18, $t = 2.57$). This means that high MSCL symptoms at baseline predicted worse 9-month residual depressive symptoms. This effect was driven by the ADM group, in that higher MSCL symptoms predicted higher residual depressive symptoms in this group, but not in the MBCT one (see Figure 3.10).

The same analyses were repeated based on the two factors of the MSCL (physical and psychological). The physical symptoms moderated the effects of MBCT vs. m-ADM groups on residual depressive symptoms at 9 months (see Figure 3.11) and marginally at post-intervention (See Table 3.4). Regarding the psychological component, no moderation effects were found in any of the follow-ups (see Table 3.5).

3.5 Discussion

In the current secondary analysis, the first aim was to explore whether MBCT could better alleviate medical symptoms (physical and psychological) compared to those on antidepressants. The second aim was to see to what extent those symptoms moderate the effects of MBCT versus antidepressant medication in terms of the depression relapse rate and residual depressive symptoms. The aim was also to establish the reliability and factor structure of the MSCL. Overall, the findings of exploratory factor analysis showed the MSCL measure loaded onto two factors (physical and psychological). Also, no differences were found between the MBCT and m-ADM groups in terms of change in the physical and psychological factors of the MSCL. Regarding the moderation analyses,

the findings largely supported the perspective that baseline medical symptoms, as assessed by MSCL, play a role as a moderator of effects of MBCT vs. m-ADM. This pattern was most clearly demonstrated in terms of relapse rate, but also emerged, to some extent, in terms of residual symptom severity with the effects hold when looking solely at physical symptoms not psychological ones.

MBCT vs. m-ADM did not help to alleviate medical symptoms (physical and psychological) at either 12 or 24 months. These findings are not in line with an uncontrolled study (Carmody & Baer, 2008) that used mindfulness-based stress reduction (MBSR) with people with chronic pain and psychological symptoms, which elicited that MBSR showed positive effects (pre-post intervention) on medical symptoms, as assessed by MSCL, with a large effect size. This could be explained by the fact that these authors used an uncontrolled design, which meant that robust conclusions could not be drawn. Also, it could have been due to the populations (recurrent depression vs. chronic pain with psychological symptoms) and interventions (MBCT vs. MBSR) being different. The current study extends the secondary results presented in Kuyken et al. (2016), as it has been demonstrated that this pattern plays out in terms of both physical and psychological symptoms.

The baseline total score of the MSCL moderated the effects of MBCT vs. m-ADM on relapse rate at 12 and 24 months. Moreover, it played a moderation role on the relationship between MBCT vs. m-ADM and residual depressive symptoms, as assessed by BDI at 12 months and HAMD at 9 months. The simple slopes for the interaction between the MSCL and groups show that participants in the m-ADM group with high medical symptoms reported high depressive symptoms at 12 and 24 months, whilst this picture was not clear for the MBCT group. Similar findings were found regarding the physical factor of the MSCL as for the participants in the m-ADM group, with high

physical symptoms reported high depressive symptoms as assessed by BDI at 12 months and HAMD at 9 months, whilst this picture did not show up in the MBCT group. Thus, the outcomes of the current study point to the potential role that medical symptoms, especially those associated with physical health, play in relation to effects of MBCT on essential depression outcomes, such as relapse and residual depressive symptoms. This is inconsistent with a study by Nyklíček, van Son, Pop, Denollet & Pouwer (2016), who examined the role of medical comorbidity on the effects of MBCT on anxiety, depressive symptoms and perceived stress in people with diabetes, finding that medical comorbidity did not have a moderation effect on the relationship between MBCT vs. a control group. One explanation for this inconsistency is that the populations were different (recurrent depression vs. diabetes with psychological symptoms). Another explanation could be due to the nature of the moderator, as in the current analysis the focus was only on medical symptoms, while in previous one they focused on medical conditions.

Interestingly, the main effects of the total MSCL and the sub-physical symptoms on residual depressive symptoms, as assessed by BDI and GRID-HAMD, were mostly significant at post-intervention, 9 and 12 months, whilst the interaction effects were not significant at some of these follow up times. This could indicate that medical symptoms, especially the physical side, did have an impact on depression outcomes regardless of the group that the participants were in. This is consistent with the literature regarding the role of medical symptoms in relation to depression outcomes (Chisholm et al., 2003; Jeong et al., 2014; Trivedi, 2004).

However, whilst the MBCT participants did not experience repaired medical symptoms when compared to the antidepressant group, interestingly, those undertaking MBCT seemed to outperform the antidepressant group in relation to the subgroups with high medical symptoms and high physical ones. One explanation for this might be that

MBCT may help with an individual's reaction to/awareness of physical symptoms rather than changing them (Dunn et al., 2010; Parkin et al., 2014).

3.6 Strength and limitations

To the best of our knowledge, this study is the first that has examined medical symptoms as a moderator of MBCT effects on depression outcomes. Moreover, the sample size used in the analyses was large. In addition, this study is the first that established the psychometric properties of the Medical Symptoms Checklist (MSCL).

However, it does have several limitations. First, the analysis was performed based on intention-to-treat (ITT) only and not per-protocol analysis. Using both methods has been recommended by the Consolidated Standards of Reporting Trials (CONSORT) (Moher et al., 2001; Schulz, Altman & Moher, 2010). Second, the role of medical symptoms as a moderator was based on a sample of people with three or more depressive episodes and thus, it is important to see whether the same moderator would show up in other populations, such as people with fewer depressive episodes or those with current depression. Third, the exploratory factor analysis carried out was based on a population with pure recurrent depression and consequently, checking the validity of the MSCL in other populations, such as people with chronic disorders might reveal a different underlying factor structure. Finally, the two-component solution of the exploratory factor analysis explained only a small proportion of the total variance.

3.7 Future research

It would be interesting to explore the role of physical health symptoms as a mediator to see if change in physical health symptoms accounts for superior acute symptom recovery and relapse prevention in MBCT versus antidepressant populations. In the current analysis, it was not possible to measure this, given that the MSCL scores were not assessed immediately post treatment. Also, it would be useful to focus on

attitude/awareness of somatic symptoms using new measures, such as multidimensional assessment of interoceptive awareness (MAIA; Mehling et al., 2012). In addition, replicating the findings in terms of the two-structure factors of the MSCL through the deployment of populations with chronic physical conditions would help to establish whether the same factors in the current study hold in this other context.

Table 3.1

Descriptive statistical of MSCL at baseline, 12 and 24 months follow up in MBCT and m-ADM groups.

MSCL	MBCT		m-ADM	
	N	M (SD)	N	M (SD)
Baseline	210	22.8 (13.9)	206	21.7 (13.7)
12 months	167	20.9 (14.0)	156	19.2 (13.7)
24 months	169	22.1 (14.6)	167	21.6 (16.2)

Note. N: number of participants; M: Mean; SD: Standard deviation.

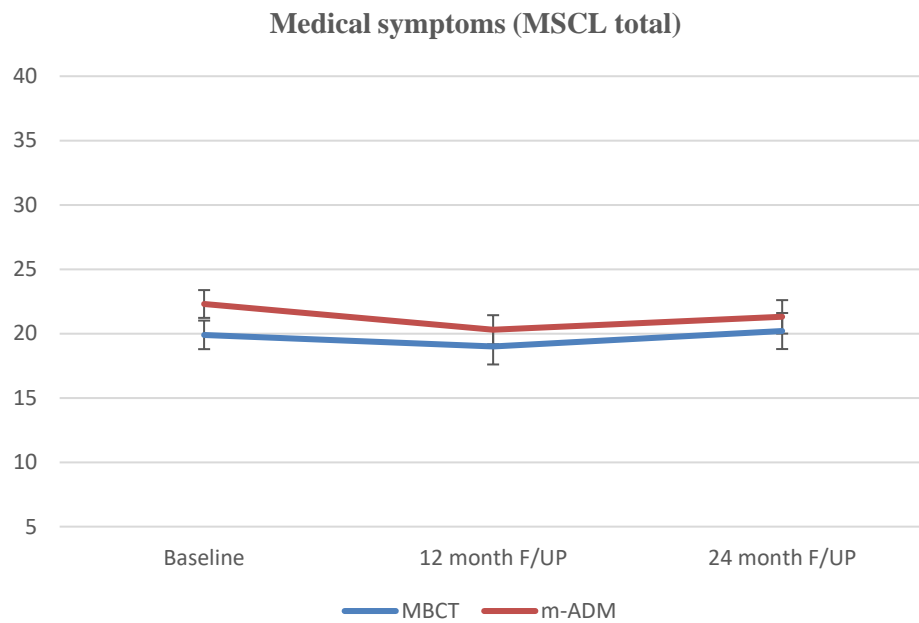


Figure 3.1. Means and SEM for the Medical Symptoms as Assessed by the Total MSCL.

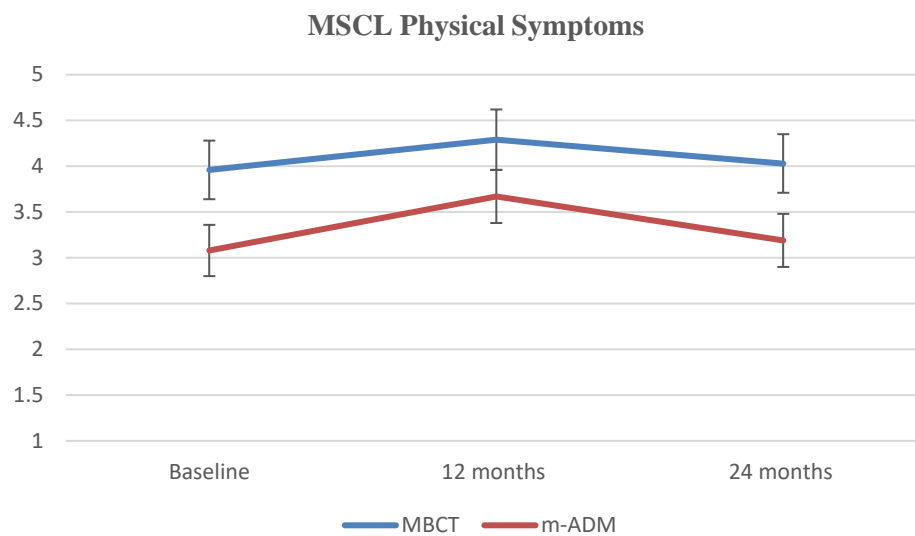


Figure 3.2. Means and SEM for Physical Factor of the MSCL (18 items)

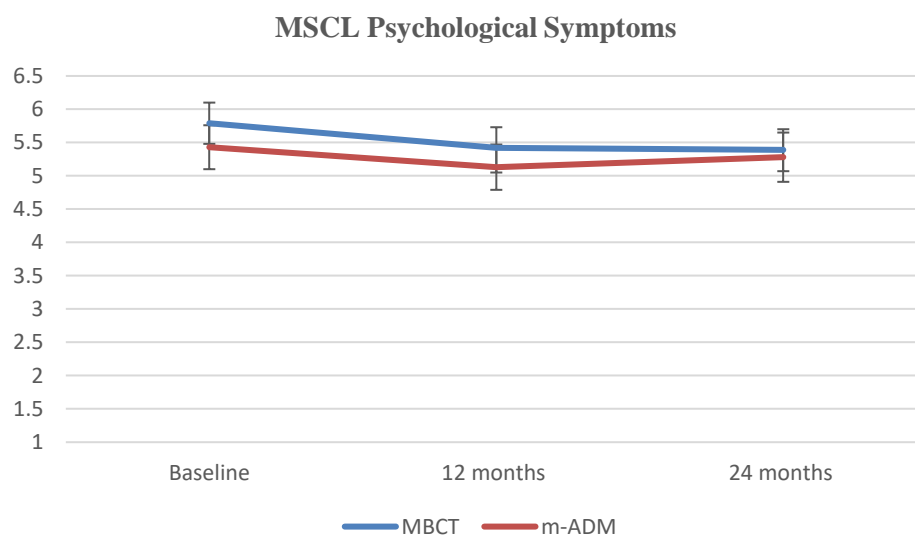


Figure 3.3. Means and SEM for Psychological Factor of the MSCL (14 items)

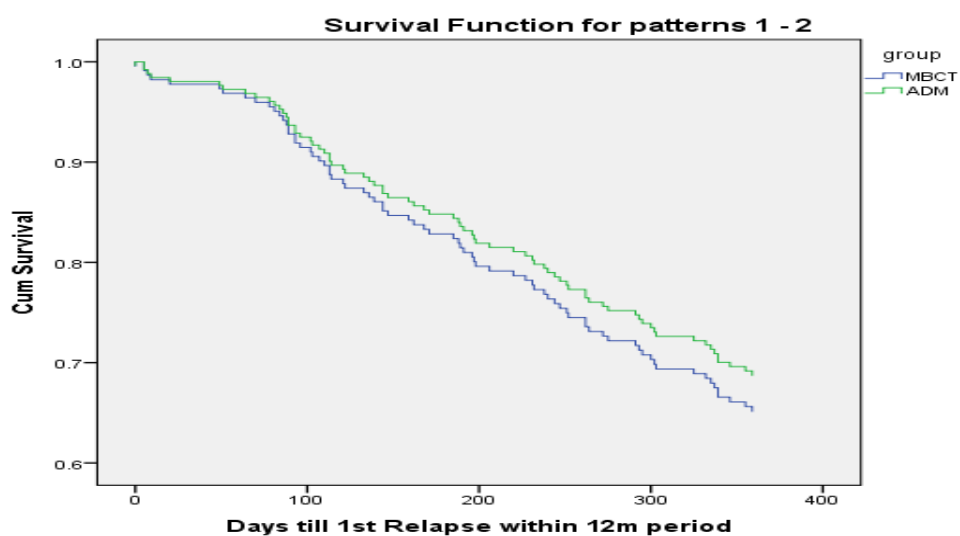


Figure 3.4 Relapse Rate in People with low Medical Symptoms at 12-Month

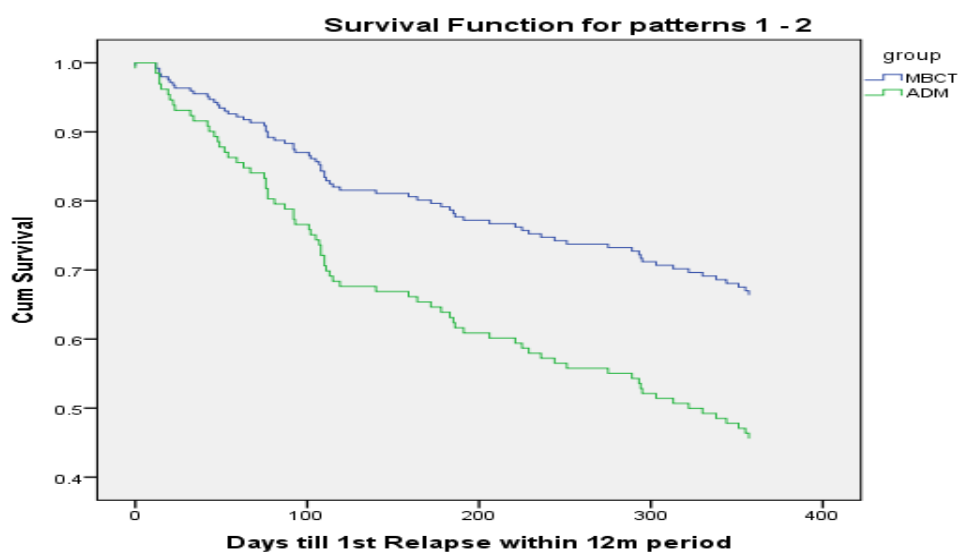


Figure 3.5 Relapse Rate in People with high Medical Symptoms at 12-Month

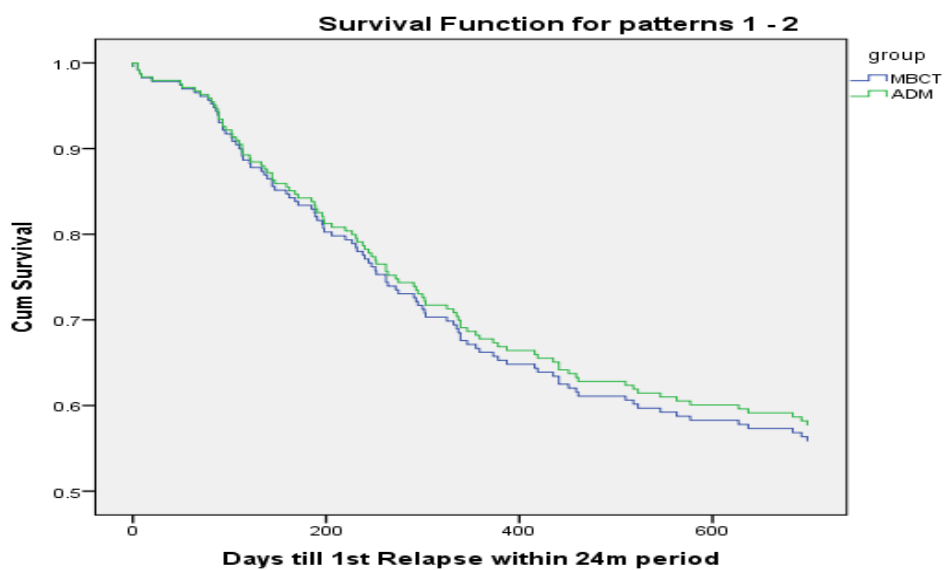


Figure 3.6 Relapse Rate in People with low Medical Symptoms at 24-Month

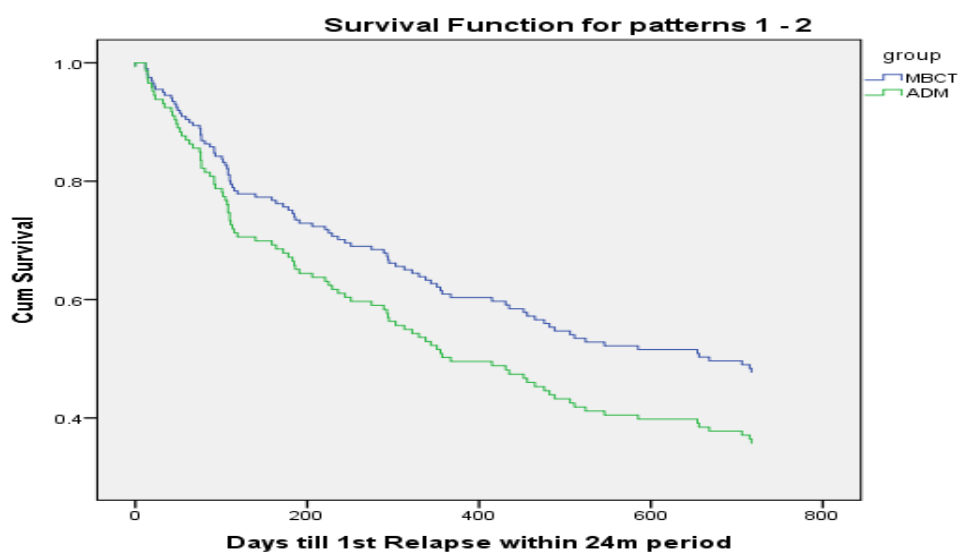


Figure 3.7 Relapse Rate in People with high Medical Symptoms at 24-Month

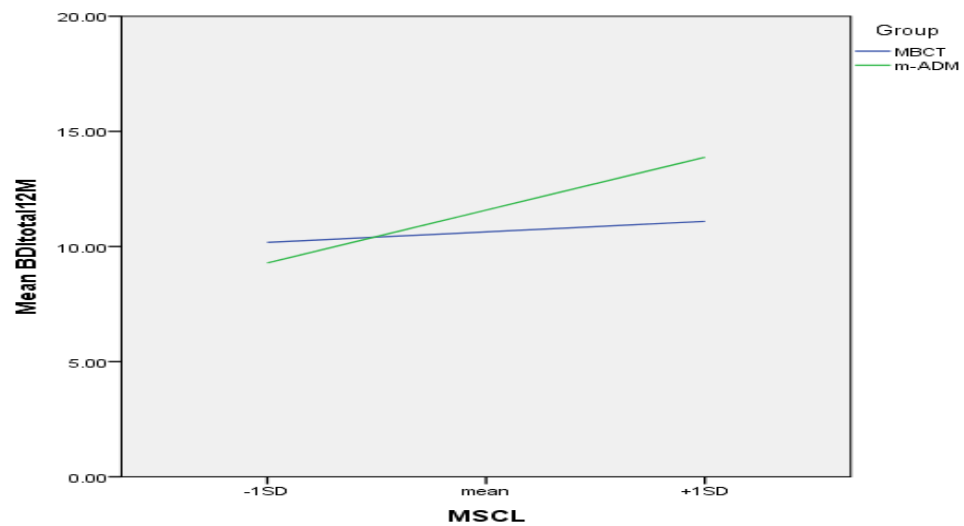


Figure 3.8. Baseline Medical Symptoms as a Moderator of Effect of MBCT vs.m-ADM on Residual Depressive Symptoms as Assessed by BDI at 12-Months

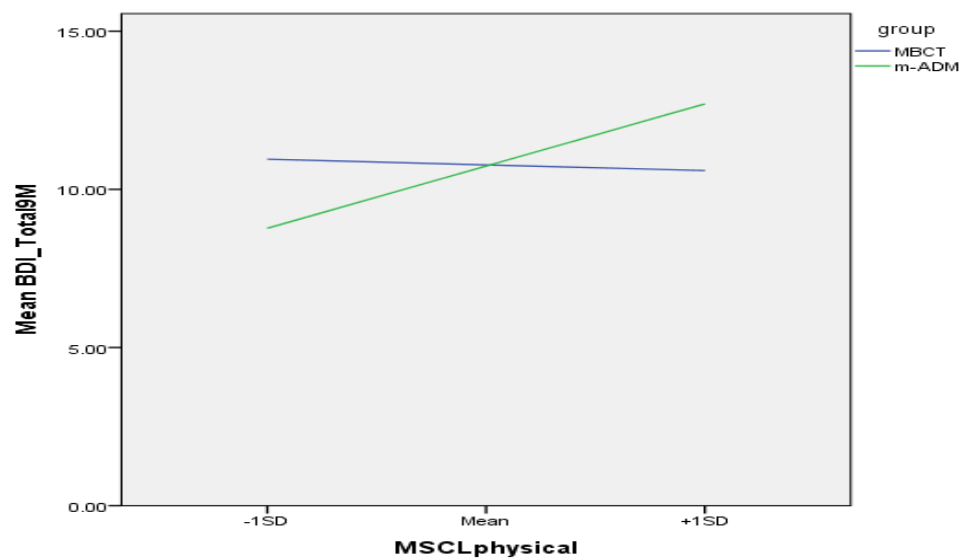


Figure 3.9. Baseline MSCL Physical as a moderator of effect of MBCT vs. m-ADM on residual depressive symptoms as assessed by BDI at 9-months

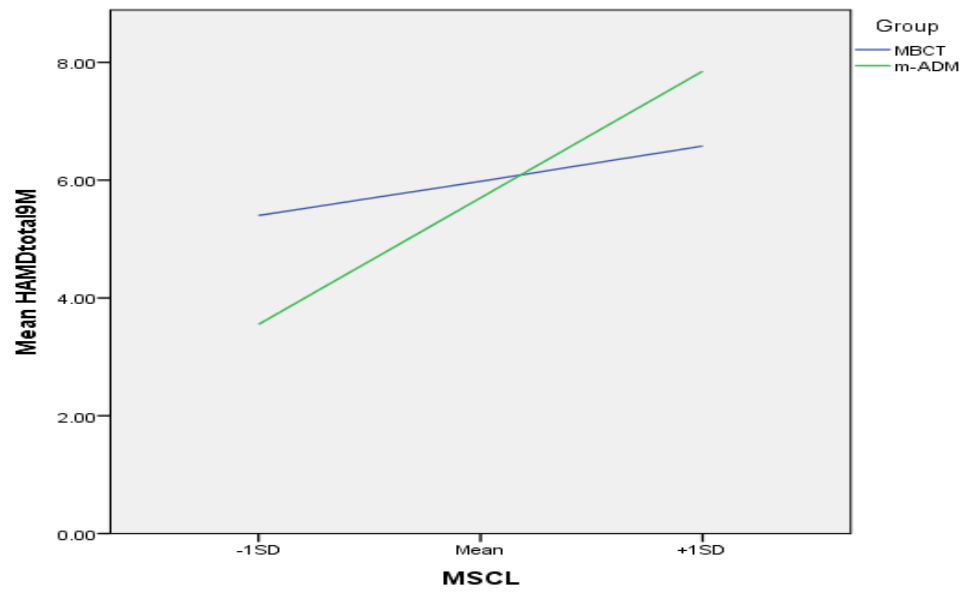


Figure 3.10. Baseline Medical Symptoms as a Moderator of Effect of MBCT vs. m-ADM on Residual Depressive Symptoms as Assessed by HAMD at 9-Months

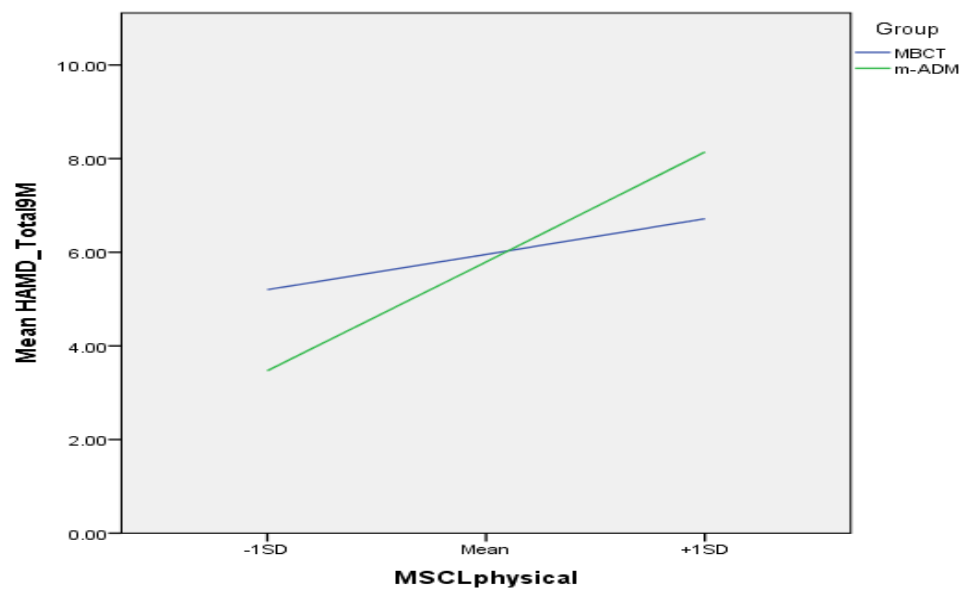


Figure 3.11. Baseline MSCL Physical as a Moderator of Effect of MBCT vs. m-ADM on Residual Depressive Symptoms as Assessed by HAMD at 9-Months

Table 3.2

Pattern matrix for the EFA with Direct Oblimin rotation of a two-factor solution for medical symptoms checklist (MSCL)

Item no	Items	F1	F2
52	Weakness in arms or legs	.538	
4	Loss of balance	.535	
5	Dizzy spells	.526	
27	Shortness of breath with normal activity	.501	
59	Itching or burning skin	.489	
56	Leg cramps	.488	
7	Blurry vision	.479	
33	Pain in abdomen	.453	
11	Eye pain or itching	.439	
50	Swollen joints	.434	
53	Painful feet	.419	
20	Wheezing or grasping	.418	
28	Swollen feet or ankles	.415	
39	Pain in rectum	.414	
42	Itching rectum	.413	
40	Hearing difficulties	.408	
13	Noises in ears	.405	
16	Back or shoulder pains	.404	
71	Worrying lot		-.674
67	Lonely or depressed		-.622
64	Difficulty making decisions		-.600
61	Nervousness or anxiety		-.590
77	Annoyed by little things		-.532
65	Lack of concentration		-.516
76	Angered easily		-.501
69	Hopeless outlook		-.484
74	Shy or sensitive		-.473
75	Dislike criticism		-.468
66	Loss of memory		-.457
73	Feeling of desperation		-.443
70	Difficulty relax		-.434
68	Frequent cry		-.405

Note. F1: Factor one (Physical symptoms); F2: Factor two (Psychological symptoms).

Table 3.3

Linear regression analyses examining the total MSCL as a moderator of the effects of MBCT vs. m-ADM on residual depressive symptoms

Outcome	Main effect				Interaction effect			
	B	Beta	t	p	B	Beta	t	p
BDI								
Post-intervention	0.11	0.15	2.67	.01	0.06	0.04	0.87	.38
9 months follow up	0.05	0.08	1.14	.26	0.12	0.11	1.55	.12
12 months follow up	0.09	0.14	2.23	.02	0.14	0.13	1.93	.05
GRID-HAMD								
Post-intervention	0.09	0.23	4.33	.00	0.11	0.09	1.31	.19
9 months follow up	0.10	0.22	4.23	.00	0.11	0.18	2.57	.01
12 months follow up	0.10	0.23	4.33	.00	0.05	0.08	1.43	.25

Note. B= unstandardised regression coefficient; Beta= standardised coefficient

Table 3.4

Linear regression analyses examining the physical symptoms of MSCL as a moderator of the effects of MBCT vs. m-ADM on residual depressive symptoms

Outcome	Main effect				Interaction effect			
	B	Beta	t	p	B	Beta	t	p
BDI								
Post-intervention	0.37	0.14	2.76	.01	0.32	0.08	1.23	.21
9 months follow up	0.20	0.08	1.31	.19	0.56	0.14	1.94	.05
12 months follow up	0.25	0.10	1.87	.06	0.49	0.13	1.91	.06
`GRID-HAMD								
Post-intervention	0.41	0.26	5.10	.00	0.27	0.12	1.75	.08
9 months follow up	0.37	0.24	4.51	.00	0.42	0.18	2.63	.01
12 months follow up	0.23	0.15	2.86	.00	0.24	0.12	1.64	.10

Note. B= unstandardised regression coefficient; Beta= standardised coefficient.

Table 3.5

Linear regression analyses examining the psychological symptoms of MSCL as a moderator of the effects of MBCT vs. m-ADM on residual depressive symptoms

Outcome	Main effect				Interaction effect			
	B	Beta	t	p	B	Beta	t	p
BDI								
Post-intervention	0.13	0.05	0.81	.42	0.16	0.05	0.68	.49
9 months follow up	0.09	0.04	0.53	.59	0.36	0.10	1.31	.19
12 months follow up	0.31	0.13	2.00	.05	0.35	0.10	1.45	.15
GRID-HAMD								
Post-intervention	0.13	0.21	4.14	.00	0.23	0.11	1.54	.12
9 months follow up	0.19	0.13	2.43	.02	0.24	0.12	1.57	.16
12 months follow up	0.62	0.18	3.55	.00	0.13	0.07	0.93	.35

Note. B= unstandardised regression coefficient; Beta= standardised coefficient.

Chapter 4.0

Study 3

Mindfulness-Based Cognitive Therapy (MBCT) for People with Depression and

Cardiovascular Disorders: Manual Development Pilot Group

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4.1 Abstract

Background: Depression co-occurs in 20 % of people with cardiovascular disorders, can persist for years, and predicts worse physical health outcomes. There is increasing evidence that psychological mechanisms, including self-efficacy, self-care, rumination and worry may explain why depression is linked to CVDs. Mindfulness-based cognitive therapy, as a mind-body treatment, has shown promising effects in a wide range of physical conditions with small to medium effect sizes. Developing a bespoke form of MBCT for people with CVDs and co-morbid depression to maximise the effect sizes and targeting some of the mechanisms linked between these conditions could prove beneficial. Developing and refining such an approach is the focus of the current work. **Methods:** This study reports an uncontrolled manual development pilot group ($n = 9$) to develop a bespoke adaptation of MBCT for individuals with depression and cardiovascular disorders. Repeated measurements of depression, mindfulness and illness perceptions were taken throughout the pilot group. **Results:** Nine people took part in the pilot group and all completed the full course, with the levels of attendance and home mindfulness practice being high. With regards to the primary outcome (depression), six out of the nine participants showed significant clinical change for the better. Some changes were made to the MBCT manual in terms of the main themes and home practice, based on feedback from the delivering therapist and participants. **Conclusions:** The findings of this pilot group seem promising in terms of adapting the MBCT manual for people with depression and cardiovascular disorders. Retention and attendance rates were high, depressive symptoms and illness perceptions were reduced, and self-reported mindfulness was increased. This suggests it is reasonable to proceed to the next level of developing MBCT for people with depression and CVDs (a feasibility

randomised controlled trial of the approach compared to another active mindfulness intervention and a control arm).

Keywords: MBCT, depression, cardiovascular disorders, manual development, pilot group.

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Conflict of interest

WK is Director of the Oxford Mindfulness Centre and until 2015 was an unpaid Director of the Mindfulness Network Community Interest Company. He is the Principal Investigator of several externally funded projects evaluating the efficacy of MBCT. AE is co-director of the Mindfulness Network Community Interest Company and teaches nationally on MBCT. The other authors declare that they have no conflict interest.

Authors' contributions

MA prepared the study materials, conducted the assessments, analysed the data and drafted the manuscript. AE revised the manual, conducted the MBCT-HeLM and commented on the manuscript. CD contributed to the study design and commented on the manuscript. BD revised the manuscript. WK conducted some of the MBCT-HeLM

sessions, revised the manual, participated in the design of the study, monitoring it, and revision of the manuscript. All authors read and approved the final manuscript.

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4.2 Background

According to the World Health Organisation (WHO), depression and cardiovascular disorders will be the leading cause of morbidity and mortality worldwide by 2020 (World Health Organization, 2012). In the United Kingdom approximately 20% of people with CVDs suffer from depression (Davidson, 2012; Huffman et al., 2013). The comorbidity between depression and CVDs is associated with worse psychological and physical outcomes and increases the burden on individuals and health service providers (Baumeister et al., 2015; Dickens, Katon, et al., 2012; Naylor et al., 2012; Pelletier et al., 2015; Rustad et al., 2013).

This comorbidity can be explained through a combination of various biological, psychological, and social factors. For instance, at the biological level increased inflammation and platelet activation have been found to be associated with both conditions (Dickens, 2015; Guarneri, Mercado, & Suhar, 2009; Miller & Blackwell, 2006). Additionally, psychological factors, such as self-efficacy, self-care, and health related concerns, have also been shown to be linked to these conditions (Greco et al., 2014; Morgan et al., 2014; Tovar et al., 2015; van der Wal et al., 2016; Volz et al., 2016). Moreover, it has been suggested that perseverative negative cognitive processes, such as worry or rumination, influence both symptoms of anxiety and depression (Nolen-Hoeksema, 1991) and are associated with CVDs such as coronary heart disease and hypertension (Gerin et al., 2012; Kubzansky et al., 1997; Radstaak et al., 2011). Consequently, psychological interventions that can target the key mechanisms underlying CVD and co-morbid depression need to be developed to improve the physical and psychological outcomes for this population.

Mindfulness interventions were developed as integrated therapies to target the mind-body relationship. Mindfulness-Based Cognitive Therapy (MBCT) has been

designed to target negative thinking styles that make individuals with a chronic history of depression vulnerable to relapse (Segal et al., 2002, 2013). A number of studies have shown that MBCT has promising effects in terms of relapse prevention and treating residual depressive symptoms, with these effects having been found to be comparable to the results for antidepressants (Kuyken et al., 2016; Segal et al., 2010). Moreover, MBCT has also shown promising results in terms of treating depressive symptoms and psychological problems in some physical conditions, including cancer, diabetes, inflammatory bowel disease (IBD) and multiple chemical sensitivities (MCS) (Schoultz et al., 2015; Skovbjerg et al., 2012; Van Der Lee & Garssen, 2012; van Son et al., 2014).

However, the evidence thus far that supports the effects of MBCT in terms of physical outcomes is mixed as well as the benefits of it being found mostly to be small in magnitude (Abbott et al., 2014). With regards to CVDs, as far as we are aware, only one non-randomised trial has evaluated the efficacy of MBCT for people with heart conditions and current depression (O'Doherty et al., 2015). The results indicated that MBCT had medium to large effect sizes on reducing current depression, anxiety, and illness perception and increasing quality of life. However, the non-randomised design used preclude strong conclusions from being drawn and thus further research is needed.

It is likely to be beneficial to develop a bespoke form of MBCT for people with CVDs and co-morbid depression to maximise the effect sizes and target some of mechanisms linked between depression and CVDs. Standard MBCT primarily emphasises specific mechanisms that apply to depression, including rumination about causes, meanings and the consequences of low mood, but individuals experiencing CVDs appear to have different cognitive patterns (Larsen & Christenfeld, 2009; Rozanski et al., 1999). For instance, they may be concerned about having another heart attack or stroke or rumination about the causes, meanings and consequences of a cardiac

condition. Moreover, due to the nature of CVDs, people may feel insecure with their body and thus, a different focus during mindfulness practice may be required.

Furthermore, existing evidence suggests that people with CVDs have low confidence regarding their ability to take care of their condition (i.e. low self-efficacy), which undermines their self-care (Greco et al., 2014; Riegel et al., 2011, 2007; Tovar et al., 2015; Volz et al., 2016). A bespoke intervention that addresses these issues is likely to be optimally effective. Developing and refining such an approach is the focus of the current paper.

The recent UK Medical Research Council guidelines (MRC) (Craig et al., 2008) suggest criteria for ensuring high quality and efficacy of developing or improving complex interventions. Also, the National Institutes of Health (NIH) stage model (Onken et al., 2014) proposes six developmental stages to follow to enhance the potency of a novel intervention and to fit into the service delivery system. Dimidjian & Segal (2015) carried out a careful review of the existing mindfulness interventions literature and conclude that mindfulness studies tend to jump to examine an intervention's efficacy or effectiveness without carefully considering the processes for improving the intervention. Therefore, the authors proposed a “mapping approach” based on the NIH stage model to assist with development of new versions of mindfulness interventions and suggested recommendations that enhance the ways of tailoring the intervention to fit a certain population, thus filling the existing gaps between research and practice.

Therefore, to ensure that any MBCT adaptations are optimally effective and likely to be implementable in practice, this study has followed the MRC and NIH models. We adapted the standard MBCT protocol for people with depression and CVDs through different phases. In the first phase, we conducted two systematic reviews (Abbott et al., 2014; Alsubaie et al., 2017) and two secondary analyses, which

established that presumably that there is a need for a novel, bespoke, MBCT that needs to carefully be mapped into specific mechanisms. The current study represents the second phase of our project “Heart and Living Mindfully (HeLM), which is aimed at developing and piloting a bespoke MBCT manual targeting depression in the context of comorbid CVD.

The aims of the HeLM pilot group:

1. Refining the standard MBCT manual so as to make it acceptable to and feasible for people with depression and cardiovascular disorders;
2. Testing the feasibility of recruitment to an MBCT course for people with depression and cardiovascular disorders;
3. Assessing the MBCT-HeLM course acceptability (e.g., rates of attendance, retention and completion assessment);
4. Assessing the weekly changes in participants’ depressive symptoms, mindfulness and illness perceptions through the MBCT-HeLM course, to see whether the course was useful to participants.
5. If these aims are met, the next stage of the project will be to conduct a feasibility randomised controlled trial evaluating this approach.

4.3 Method

4.3.1 Manual Development

The HeLM- MBCT manual was developed across different stages and involved conducting two pilot groups. The aim of this work was to make it applicable for people with depression and cardiovascular disorders, with the hope that these changes would meet some of the needs of this population. During the first stage of developing the manual, monthly meetings were held between HeLM projects members, who have expertise in mindfulness interventions and cardiovascular problems over seven months (January to July 2013). Through these meetings, the original MBCT manual was reviewed and the best ways to make it more appropriate for people with cardiovascular disorders were discussed in detail. The first meeting of this series, involved two members of a Public and Patients Involvement (PPI) group who had experience with depression and cardiovascular disorders. The lead researcher attended all the meetings in addition to completing a study that formed the first phase of the HeLM project as part of the lead researcher master's degree.

For the second stage of developing the manual, a first pilot group was conducted in July/Aug 2013 using the first draft of the manual. The group comprised three members of the HeLM team as well as people from the PPI group and eight patients (people with depression and cardiovascular disorders). The aim of conducting this group was to identify any changes to the manual that were necessary through discussions between the HeLM members, PPI group and people with cardiovascular disorders week by week base throughout the course. More details about this group are presented in Appendix A.

In the third stage of developing the manual, we conducted the second pilot group in October/Nov 2014 using the second draft after making the changes. Weekly meetings

were held after each session between the therapists (WK and AE) and the lead researcher (MA) to discuss the manual.

4.3.2 Study Design

This study is an uncontrolled group with repeated measurements of depression, mindfulness and illness perceptions throughout the HeLM-MBCT course.

4.3.3 Inclusion and Exclusion Criteria

Inclusion criteria for this group were as follows: (a) adults aged 18 and older; and (b) a diagnosis of a cardiovascular disorder (heart conditions or stroke); c) a history of depression (major depressive disorder) and/or low grade depressive symptoms. We excluded people who were currently depressed (given that the standard MBCT course has been designed to target people with recurrent depression who are in a remission phase), had co-morbid diagnoses of current substance dependence or abuse, had organic brain damage, had current or past psychosis, exhibited persistent antisocial behaviour, and carried out persistent self-injury and those who were engaged in formal psychotherapy.

4.3.4 Recruitment

One of the main aims of conducting this pilot group was to test the feasibility of recruitment to an MBCT-HeLM course for people with depression and cardiovascular disorders. Different strategies to recruit people to this group were used. First, the researchers (MA and RV) visited the inpatient cardiology ward at the Royal Devon and Exeter hospital to explain the study to cardiac nurses and to ask them to refer potential people to the group. Second, MA attended the outpatient's clinic at the cardiology department once weekly (mornings and afternoons), for five weeks. During these visits, the study was explained to 32 people with given them a poster and a reply form that they could fill it out and return to the researchers using the free envelope supplied. Third, the

study summary was emailed to the AccEPT Clinic/Mood Disorders Centre top referring GPs to inform them what the research would entail. We also posted this to the north Devon cardiac nurse and the Stroke Association with freepost return envelopes for any person wishing to participate. Fourth, we distributed the poster in some shops and fitness centres in Exeter with phone and address contact details. In the screening phase, the researcher (RV) screened all interested people via phone to assess their eligibility, based on the inclusion and exclusion criteria of the pilot group. The summary of study was resent to all interested and eligible people along with an invitation to an orientation session with (WK). The group's starting date had to be rescheduled twice, from October 2013 to May 2013 and then October 2014 due to difficulties in recruiting people.

4.3.5 Adapted-MBCT Course (HeLM)

The adapted-MBCT group was conducted by qualified therapists (WK and AE) with experience in running mindfulness interventions. This adapted course involved one orientation session (1 hour) plus eight weekly sessions lasting 2.5 hours. The therapists used the second draft of HeLM manual, which, as aforementioned, was modified based on the PPI group and the comments made by those who attended the first pilot group. Participants were provided with CDs to help them practise at home, which they were encouraged to do for six days per week. The home practice sheets were seen by the therapist session by session and a copy of them was added to the participants' folders. In addition, three measures were applied before and after the course as part of the AccEPT Clinic/ Mood Disorders Centre routine.

4.3.6 Weekly Assessments

Weekly assessments were conducted to assess changes in depression, mindfulness and illness perceptions, with the aim of seeing whether the adapted-MBCT (HeLM) course was helpful for people with depression and cardiovascular disorders.

4.3.7 Outcomes

Demographic data collected included: age, gender, ethnicity, marital status, and type of cardiovascular disorder. Three questionnaires were administered at baseline, weekly during the course, at the end of the group and three months after the completion of the group. Given this study is important as it is one of the first that targets people with cardiovascular disorders and due to the difficulties in recruiting people that we had, we decided to reduce the burden on participants as much as possible so as maximise retention by using three measures with less items in each of them. Depression was assessed as the primary target of this course. We used illness perceptions as a secondary outcome, as there is evidence that people's beliefs can affect the efficacy of any treatment and also their level of compliance with it (Petrie et al., 1996; van der Wal et al., 2016). Finally, we chose to assess mindfulness skills as these are the main target of all the mindfulness interventions.

4.3.7.1 The Patient Health Questionnaire-9 (PHQ-9).

Depressive symptoms were assessed using the Patient Health Questionnaire-9 (PHQ-9; Spitzer, Kroenke, Williams, & Group, 1999). Each of 9 items describing the core symptoms of depression are scored between 0 (not at all) and 3 (nearly every day) with total scores ranging between 0 and 27. The cut-off points of the PHQ-9 are 5, 10, 15, and 20, which reflect none/minimal depression (0-4), mild depression (5-9), moderate depression (10-14), moderately severe depression (15-19), and severe depression (20-27) respectively. The PHQ-9 has adequate reliability and validity in

primary care in the UK (Cameron, Crawford, Lawton, & Reid, 2008) as well as for people with coronary heart disease (Haddad et al., 2013).

4.3.7.2 Five Facet Mindfulness Questionnaire (FFMQ).

The five facet mindfulness questionnaire (FFMQ; Baer et al., 2006) was designed to assess different aspects of mindfulness. It consists of 39 items, reflecting five facets: non-reactivity to inner experience, observing, acting with awareness, describing and non-judging of experience. Each item is rated on a 5-point Likert scale, ranging from 1 (never or very rarely true) to 5 (very often or always true). The FFMQ has good internal consistency, with Cronbach's alpha between 0.72 and 0.92 for the five facets (Baer et al., 2006, 2008).

4.3.7.3 Illness Perception Questionnaire-Brief (IPQ-Brief).

The illness perception questionnaire-brief (IPQ-Brief; Broadbent, Petrie, Main, & Weinman, 2006) was used to assess participants' beliefs about their illness. This is a short form of the illness perception questionnaire (IPQ) that was developed to assess cognitive representations. The IPQ-brief contains 9 items that assess time line acute/chronic, time line cyclical, consequences, personal control, treatment control, illness coherence (understanding) and emotional representations. Each item is scored between 0 (no affect at all) and 10 (severely affects my life)¹³. The IPQ-brief has good validity and reliability (Broadbent et al., 2006). We used the short form of IPQ as it is appropriate for repeated measures design and to decrease the burden on the participants.

¹³ Low scores on IPQ-Brief represent improvements.

4.3.8 Data Entry and Management

4.3.8.1 Entering data and dealing with missing data.

The data were entered into SPSS version 22.0 To deal with missing data, the instructions provided in the measure manual, if applicable, were followed. We used multi-imputation to replace missing data as suggested by Rubin (1996), which involves calculating an average of items and then replacing the missing data with it.

4.3.8.2 Cleaning data.

The cleaning of the three measures (PHQ-9, IPQ-brief and FFMQ) was carried out through two steps. First, we checked each measure in terms of item range, total score ranges and the subscale score ranges. Second, we checked the outliers and the normality. As we had one group with pre-and post-scores, a difference score for pre-and post-intervention was computed first and then the normality and outliers for the difference in scores were checked. The data cleaning protocol is presented in Appendix C.

4.3.9 Statistical Analysis

The characteristics of the participants were summarised using the means and standard deviations for the continuous variables and percentages for the categorical ones. Due to the absence of a control group and the small sample size in this pilot study, the study data were analysed using three methods. First, we calculated the pre- and post-intervention means, SDs, Cohen effect sizes (Cohen, 1992), and confidence intervals for PHQ-9, FFMQ and the IPQ-Brief. This method is recommended by the guidelines for good practice in designing, analysing and reporting pilot and feasibility studies (Lancaster, 2015; Lancaster, Dodd, & Williamson, 2004). Second, we used the clinically significant methods (the cut-off points of PHQ-9 and reliable change index (RCI; Jacobson & Truax, 1991) that consider individuals' changes across time. Specifically, the cut-off points method measures that whether the individuals are in the clinical or non-

clinical range. The reliable change index (RCI) formula of Jacobson & Truax, (1991) was used as an indication of the improvement in each participant. Third, graphs representing the weekly changes in depression, mindfulness and illness perceptions for each participant were created.

4.4 Results

4.4.1 Recruitment

12 people were recruited between February and July 2014 through referrals from the outpatient's clinic (PCI) at the cardiology ward ($n = 5$) and cardiac rehab at the Royal Devon & Exeter Hospital ($n = 3$), cardiac nurses in North Devon ($n = 3$) and the Stroke Association ($n = 1$). One participant died before the orientation session and two people were excluded during it as they had current depression. Nine participants gave their written consent and took part in the group.

4.4.2 Manual Development

The adaptations were made to the manual and hand-outs with regard to the main themes, meditation practices and home exercises. In the adapted manual, there is more emphasis on encouraging people to have more positive feelings about their body, taking care of the self and getting to know reciprocal relationship of stress/low mood/anxiety and bodily experience. In addition, there is consideration of how to adjust to living with a long-term condition. For more details of this manual see Table 4.1 as well as Chapter 5.0.

4.4.3 Demographic Data

Table 4.2 shows the demographic data of the pilot group. The average age of the nine people in the group was 58.78 years ($SD = 11.1$). Seven participants were males and two females. Eight were white British and one was Asian-British. Six participants were married, one was single and three were divorced. Eight out of the nine participants had

heart conditions while one woman had had a stroke. Five out of the eight people with heart conditions had had a heart attack. Three participants had more than one cardiovascular disorder (heart condition and hypertension).

4.4.4 Acceptability Results

4.4.4.1 Course completion and attendance.

There were no dropouts (0 %) with high rates of attendance: five participants (56 %) completed all eight sessions, while the other four (44 %) attended seven.

4.4.4.2 Completion of assessments.

With regards to completing the weekly assessments, four participants completed all ten (one baseline, eight sessions and one follow up), while five completed between six and nine assessments.

4.4.5 Efficacy Estimates

4.4.5.1 Means, SDs, effect sizes and confidence intervals.

Table 4.3 and 4.4 show the means, standard deviations, effect sizes and confidence intervals for PHQ-9, IPQ-Brief and FFMQ at baseline, post-intervention and three months follow up. The mean PHQ-9 score prior to the course was 10.8 ($SD = 4.9$), reducing to 4.2 ($SD = 2.9$) and 2.0 ($SD = 2.6$) after the course and at the three-months follow up consecutively. The mean baseline FFMQ was 112 ($SD = 12.4$), increasing to 143.2 ($SD = 20.2$) and 146 ($SD = 17.1$) after the course and at the three-months follow up, consecutively. The IPQ-brief score prior to the course was 41.0 ($SD = 12.6$), while it was 36.1 ($SD = 12.4$) and 32.1 ($SD = 8.1$) after the course and at the three-months follow up, consecutively. The effect sizes for PHQ-9 and FFMQ were large, while that for IPQ-Brief was small.

4.4.5.2 Clinical significance methods.

4.4.5.2.1 Cut-off points method. As a group, the baseline mean of PHQ-9 indicates that the group mean was within the moderate level. However, the post-intervention and follow up means reveal that the group means moved to the non-depressed level. Individually, it can be seen in Table 4.5 and 4.6 that eight out of the nine participants scored above the cut-off points for PHQ-9 (< 5) at baseline. After the course the findings show that six of the nine participants showed a clinically significant change. Of the two participants that did not show a clinically significant change after the course, one of them moved from a moderate to a mild level and the other one moved from a severe to a mild level. At the three months follow up, five of the seven participants who completed the follow up assessment showed a clinically significant change, while one moved from a moderate to a mild level.

4.4.5.2.2 The reliable change index method (RCI). This method was developed by Jacobson and Traux (1991), who proposed a formula¹⁴ to assess how much change has occurred during the course of an intervention. If the change is ≥ 1.96 , this indicates that the participant has improved (i.e., falls outside the 95 % confidence interval for baseline scores). As shown in Table 4.7, five participants showed a reliable clinically improvement for PHQ, while the rest did not at the post course assessment. At the three months follow up, five participants showed a reliable clinically improvement for PHQ, while the rest did not.

¹⁴ RCI formula: Client post-score - Client pre-score / S_{diff} ;
 $S_{diff} = \sqrt{2(S_E)^2}$; $S_E = SD \text{ pre} \times \sqrt{1-r}$.

4.4.5.3 Graphs of weekly changes.

Graphs of weekly changes in PHQ-9, FFMQ and IPQ-Brief for each participant in the MBCT-HeLM pilot group are presented at the end of the Chapter.

4.4.5.3.1 Summary of the PHQ-9 weekly scores. At baseline, the participants' scores on the PHQ-9 varied from 4 to 21, with the majority falling within the level of moderate depression. Throughout the course, seven out of the nine participants showed a gradual decrease in their depressive symptoms, while two maintained the same score from the first week until the follow up session. Some increases in depressive symptoms were observed in the middle of the course for two participants in week 4 and 5, and for one in week 4. In sum, all participants who completed the PHQ-9 follow-up had a reduction in their score when compared to their baseline score.

4.4.5.3.2 Summary of the FFMQ weekly scores.

4.4.5.3.2.1 FFMQ total. At baseline, the participants' total scores on FFMQ varied from 98 to 133. Five out of the nine participants showed an increase in their scores from baseline to post-intervention and follow up, while four did not experience any change throughout the course. One woman showed a substantial improvement in her mindfulness skills as she scored 98 at baseline, which went up to 167 at follow up.

4.4.5.3.2.2 Observe subscale. The participants' scores on the observe subscale varied at baseline. Five participants showed an increase in their scores from baseline to post-intervention and then to follow up. Four did not show any changes in their scores throughout the course, with two participants showing decreases in weeks 4 and 5.

4.4.5.3.2.3 Describe Subscale. At baseline, the participants' scores for the describe subscale varied. Three showed an increase in their scores from the baseline to the follow up, whilst one had a lower score on this subscale compared to other

participants, which did not change throughout the course. Other participants did not show any improvement throughout the course.

4.4.5.3.2.4 Act with Awareness Sub-scale. At baseline, three participants had high scores on this subscale, whilst three others started with low scores and these did not change throughout the course. One participant scored lower than the other participants at the baseline, gradually decreasing more until week 5 and then showed an increase in weeks 6 and 7.

4.4.5.3.2.5 Non-reactivity Subscale. The participant's scores on this subscale were similar at baseline. Four showed increases at follow up, whilst one who had a slightly lower score on this subscale. Other participants did not show any change throughout the course.

4.4.5.3.3 Summary of the IPQ-Brief. At baseline, the participants' total scores on IPQ-Brief varied from 21 to 62. Three out of the nine participants showed a decrease in their scores from baseline to post-intervention and follow up, while the others did not experience any change.

4.5 Discussion

The main aims of this pilot group were to refine a bespoke MBCT course for people with depression and cardiovascular disorders and to assess its acceptability for this population. We also aimed to test the feasibility of recruitment to this course and to see whether the course was helpful for participants in terms of decreasing depressive symptoms, negative illness perceptions and increasing mindfulness skills.

Some changes were made to the original MBCT manual in terms of the main themes, meditation practices and home exercises, with there being more focus on self-care, self-efficacy and the adjustments to having a long-term health condition.

Recruiting people to this pilot group was challenging and difficult with a one-year delay in running it due to failing to find a sufficient number of participants. We used different strategies to recruit people with cardiovascular disorders, but with focus was mainly on specialist centres, such as the cardiology department at the Royal Devon & Exeter hospital and a cardiac nurse in North Devon. These methods of recruitment were costly in terms of time (six months of recruitment with approximately two participants acquired per month). Regarding GPs, even though we asked some of GPs to refer potential participants, the efficiency of the recruitment of people through GPs were not tested.

The rates of retention and attendance in this pilot group were very encouraging; no dropouts with a high attendance rate. The participants were highly committed to the home practice and most completed all the ten assessments. It seems that the course did not cause any harm and was well-tolerated.

While caution needs to be taken when interpreting outcomes of a pilot group with this size, preliminary evidence suggests the course is helpful for participants. The effect sizes found in this group were large in terms of decreasing depressive symptoms and increasing mindfulness skills. Moreover, the clinical significance methods used with this group considering individuals' differences have shown promising results in terms of decreasing depressive symptoms. However, the uncontrolled design that was used in this study along with the small number of participants means these results require replication.

With regards to measures, the changes that were noticed for PHQ-9 across the MBCT-HeLM course indicated that this measure was sensitive to change in this particular population. The scores on the FFMQ varied substantially across the subscales and participants. However, some participants had improved scores on observe, describe, act with awareness and non- reactivity subscales by end of the course. Hence, the FFMQ

measure showed a good sensitivity to change throughout the MBCT-HeLM course. With regards to IPQ-Brief measure, when considering the total of the IPQ-Brief scores, no significant changes were found. However, when the subscales were analysed it was noticed that some participants experienced decreases after the MBCT-HeLM course. That is, some of their negative beliefs would appear to have been diminished. These results suggest future research may wish to focus on the subscales of IPQ rather than the total score.

4.6 Limitations and recommendations for future research

This group has achieved its goals in terms of refining the MBCT manual for people with depression and CVDs, checking its usefulness, acceptability and testing ways to recruit people with CVDs. However, one main limitation should be mentioned regarding the design. The absence of control group means that the reductions in depression, changes in negative illness perceptions as well as increases in mindfulness skills could be explained by other factors not specifically related to MBCT-HeLM. These results are encouraging enough to now move onto the next level of developing the MBCT manual for this population (the feasibility trial).

Also, some considerations that should be done in the next level. For example, in terms of inclusion criteria related to depression, the main criterion to recruit people was history of major depressive disorder with or without current depressive symptoms. However, other types of depression such as dysthymia or minor depression are considered to be very prevalent and cause high burden on people with CVDs (Davidson, K.W., 2012; Holzapfel et al., 2009). Therefore, the inclusion criteria will be reviewed to include such types of depression. Moreover, assessing depression was not based on a standard interview therefore, it will be important for the feasibility study to use a standard clinical interview. Also, it was clear that recruiting people through cardiac

specialist services or referrals from GPs are time costly therefore using other methods such as asking GPs to screen their records and then send letters to potential participants it might increase the number of approached people.

In summary, the findings of this pilot group seem promising in terms of adapting the MBCT manual for people with depression and cardiovascular disorders, retention and attendance rates, decreasing depressive symptoms and illness perceptions and increasing mindfulness. These outcomes have encouraged the HeLM team to proceed to the next level of developing MBCT for people with depression and CVDs (A feasibility RCT of the approach compared to other active treatments). However, the challenges of recruitment should be held in mind and this is the major uncertainty the feasibility trial will need to focus on.

Table 4.1

MBCT-HeLM manual development: MBCT outline, adaptations and case Illustrations

Session	MBCT for prevention of depressive relapse	Adaptations through piloting	Individual stories
Orientation Session Main themes	Learn about the factors associated with the onset and maintenance of depression	Learn about the factors associated with the onset and maintenance of long term physical and mental health problems	
Agenda	<p>Explain background aims of MBCT</p> <p>Outline the structure of the MBCT programme</p> <p>Emphasise that MBCT will require hard work and the need for patience and persistence in the work</p> <p>Determine if client is likely to benefit</p>	<p>In addition:</p> <p>Learn about the way the person's physical health has affected their mental health and vice versa</p> <p>Introduce the journey/map/road block and oxygen mask metaphors</p> <p>Extra background information includes:</p> <p>the idea of symptoms as a guide from the body and how mindfulness and self-care are ways of responding to these messages (navigating the road blocks of living with a long-term health condition)</p> <p>reacquainting with the body in a positive way</p> <p>moving from reactivity to responsiveness</p>	<p>There was a lot of variety in the extent to which physical health and mental health were related, with some people having long mental health histories and late onset vascular disorder and others having had a lot of trouble adapting to their changed health status post MI/stroke.</p>

Table 4.1 cont.

MBCT-HeLM manual development: MBCT outline, adaptations and case Illustrations

Session	MBCT for prevention of depressive relapse	Adaptations through piloting	Individual stories
Session 1 Main Themes	Seeing the significance of autopilot in our lives Seeing how bringing awareness to experience change the experience Building a supportive environment Introducing the course Intentions for taking part in the group Problems can be worked with MBCT for depressive relapse	Emphasis on gently turning towards bodily experience Widened to MBCT for people with vascular disorders and associated low mood, stress and anxiety Focus on all that is right with the body Before introductions coming into the body Before the raisin coming into the body with some gentle stretches	In the raisin and body scan a woman used the practice to become more aware of the way her body had been affected by stroke, and how worry thinking could be problematic. Experienced in both practices being with those symptoms in a way that was "okay." "P" talked about NFP, normal for P, acknowledging that impairment and symptoms were normal. This was significant because he described grieving/loss for the former P. A man described in the body scan developing a sense of an "innocent" relationship with his body, i.e. experiencing his body as it is not caught up in high states of worry/anxiety/self-judgment. Two participants talked about shallow breathing / tight shoulders that eased during the practice - this was new for them. Sense of new possibilities.

Table 4.1 cont.

MBCT-HeLM manual development: MBCT outline, adaptations and case Illustrations

Session	MBCT for prevention of depressive relapse	Adaptations through piloting	Individual stories
Session 1 Meditation Practices	Eating meditation (raisin) Body Scan	Brief coming in to the body before introductions. Brief movement prior to the raisin exercise Extra guidance about ways of lying, sitting for the practice	
Other exercises	Setting guidelines Introductions Feedback and discussion of raisin exercise Feedback and discussion of body scan Finish with 2 – 3 stages focusing on the breath	Outline of heart condition in introductions	
Home Practice	Body Scan Be mindful of a routine activity Eat one meal mindfully	2 versions of body scan approximately 30 and 20 minutes in duration	

Table 4.1 cont.

MBCT-HeLM manual development: MBCT outline, adaptations and case Illustrations

Session	MBCT for prevention of depressive relapse	Adaptations through piloting	Individual stories
Session 2 Main Themes	Working with difficulties in a new way Coming home to the body Seeing the layers, we add to experience Focus of attention shows the ‘chatter’ of the mind. Relationship between thoughts and feelings and the way this affects mood	Importance of taking care of ourselves (and the issues this can raise). Adapted to pick up issues related to symptoms, interpretation of symptoms, taking care of self and obligations to others	Really nice examples of importance of first and second reactions (2 darts) (emotional and cognitive) in the thoughts and feelings exercise. Importance of putting oneself first quite novel for many, the oxygen mask analogy worked well here. We also shared how in the body scan her arm had been very achy to begin and calling for attention. She was able to attend to the rest of her body and when she got to her arm it no longer ached so much.
Meditation practices	Body Scan Mindfulness of Breathing	Guiding around the heart area in the Body Scan	
Other exercises	Thoughts, feelings and sensations exercise	New scenario “You wake up in the morning and you feel unwell and very tired (but you’ve got important plans, which also involve other people and you are not sure you can even get out of bed”	
Home Practice	45-minute body scan 6/7 days 10 minutes’ mindfulness of breathing 6/7 days. Routine activity. Focus on and record pleasant events		M spoke of enjoying the sensations in the body. W spoke of how ‘shocking’ it was to see how difficult it was to find time for the BS practice and yet juicing was her routine activity and she could see how it nourished her in many ways to take this time.

Table 4.1 cont.

MBCT-HeLM manual development: MBCT outline, adaptations and case Illustrations

Session	MBCT for prevention of depressive relapse	Adaptations through piloting	Individual stories
Session 3 Main Themes	The body is a place to be with experience Awareness that the mind can be busy and scattered Taking awareness intentionally to the breath Discovering 'being present'	Heart / breathing during mindful movement	Older male described how he had become aware how low mood was associated with his shoulders stooping and some changed sensations in his chest, but was quite avoidant of discussing these. He was able to describe a sense of chest "congestion" in the torso with associated worry thoughts.
Other Exercises in Session	Practice Review Home Practice review including inquiry of pleasant events	Use body diagram with pleasant events feedback	
Meditation Practices in Session	5 minutes seeing or hearing exercise 30-40-minute sitting meditation 3 stage breathing space Mindful stretching and review Mindful walking and review	Changing order of practice 20 mins of gentle mindful movement covering movements on the CD after seeing/hearing practice. Shortened sitting practice – 15 -20 mins' posture, breath and body. No walking	Noting how the body was more limited than perhaps it had been in the past, and a sense that this needed to be accepted. One middle-aged male described how the movement was really enjoyable.
Home Practice	Stretch and breath practice on days 1, 3 and 5. Mindful movement practice on days 2, 4 and 6. Keeping a daily record of the experience of unpleasant events 3 stage breathing space 3 times each day	Short sitting practice instead of stretching and breath. Option to continue with Body scan instead of mindful movement. Encourage noticing of unpleasant events connected with vascular disorder	

Table 4.1 cont.

MBCT-HeLM manual development: MBCT outline, adaptations and case Illustrations

Session	MBCT for prevention of depressive relapse	Adaptations through piloting	Individual stories
Session 4 Main Themes	MBCT for prevention of depressive relapse The mind is mostly scattered when trying to cling to some things/ avoid things. Becoming aware of the tendency to react with aversion Mindfulness offers a way to be present – offers another place from which to view things. Developing awareness of ways to respond to stressful situations/experiences Getting to know territory of depression	Getting to know the territory of stress/low mood/anxiety and how it relates to bodily experience in a reciprocal relationship. Use the RAIN acronym (Recognise, Allow, Inquire and thoughts are Not facts), with the first stage being recognition when fear and aversion arise.	Some of the more driven qualities (and busyness) that might be present in this population manifest in the practice and approach to the practice. A woman became very aware of how external events are registered / manifest in the body, e.g. racing heart. Group resonated with the automatic thoughts, with a sense of tension and mood change. For some this was resentment / anger, possibly picking up underlying “hostility.” Real sense of common humanity in the decentering. Only this week was there more of an opening up of vulnerability.
Meditation Practices in Session	5 minutes seeing or hearing 40-minute sitting meditation 3 stage breathing space and review	Reduced to a 30-minute sitting (Choice less awareness not included) Walking practice 3 stage breathing space	

Table 4.1 cont.

MBCT-HeLM manual development: MBCT outline, adaptations and case Illustrations

Session	MBCT for prevention of depressive relapse	Adaptations through piloting	Individual stories
Session 4 Other Exercises in Session	Practice Review Home Practice Review Review of unpleasant events. Defining Territory of Depression – Automatic thoughts questionnaire and diagnostic criteria for depression Watch 1st half of MBSR video	‘Body’ diagram used to review unpleasant events calendar Adapted version of automatic thoughts used Selected clips from ‘Healing from within’ video – Link given to view whole programme Introduce RAIN acronym Introduce second arrow metaphor	
Home Practice	Sitting meditation CD 6 out of 7 days 3 stage breathing space – regular (3 times a day) 3 stage breathing space – responsive (when notice unpleasant	Alternating full sitting CD (30 minutes) with mindful movement or walking Recognising where stress is in the body using the ‘Body’ diagram	

Table 4.1 cont.

MBCT-HeLM manual development: MBCT outline, adaptations and case Illustrations

Session	MBCT for prevention of depressive relapse	Adaptations through piloting	Individual stories
Session 5 Main Themes	Bringing a sense of allowing things to be Acceptance	<p>Title of session changed to ‘Softness and Strength.’</p> <p>The RAIN acronym progresses here to the A and possibly the I directed towards bringing in a difficulty linked to the physical / mental health interface. This is the session where themes around fear/hyper-arousal or sadness/loss may well be picked up more fully with a view to beginning to really decentre from the proliferation and over-identification.</p> <p>Metaphor of the second dart explored in the "I" or inquiry.</p> <p>Being mode as a vehicle for this shift and “insight.”</p> <p>Building sense of self-care (reminding people of the oxygen mask if necessary).</p>	<p>Woman with stroke described pins and needles sensations in her head, which were linked to stress. She used a light touch breathing space that broke the cycle of escalating stress.</p> <p>Another man whose normal mode was to be lost in proliferative worry thought, had a real awakening to the impact of his heart attack.</p> <p>In the body diagram a lot about body sensations, usual sensations in chest, stomach, neck, head. But associated thoughts really linked to heart disease “can I afford to get this stressed,” “people wanting my time, but I may not have a lot of time left” with associated feelings of being overwhelmed, broken, isolated, injustice.</p>
Meditation Practices in Session	30 – 40-minute sitting meditation – introducing difficulty. Breathing space and review. 3 stage breathing space – coping and review.	Short standing at beginning of sitting practice	

Table 4.1 cont.

MBCT-HeLM manual development: MBCT outline, adaptations and case Illustrations

Session	MBCT for prevention of depressive relapse	Adaptations through piloting	Individual stories
Session 5 Other Exercises in Session	Practice Review Home Practice Review Read Rumi's poem the guest house Watch second half of MBSR video	Feedback on the Body diagram – linking the physical barometer with the body diagram to identify impact of stress. Selected clips from 'Healing from within' video that speak to allowing and softness/strength.	
Home Practice	Sitting meditation 6 out of 7 days (use CD days 1, 3 and 5 use no CD days 2, 4 and 6) 3 stage breathing space regular (3 times a day) 3 stage breathing space- responsive (whenever notice unpleasant feelings).	Optional 'working with difficulty' CD	

Table 4.1 cont.

MBCT-HeLM manual development: MBCT outline, adaptations and case Illustrations

Session	MBCT for prevention of depressive relapse	Adaptations through piloting	Individual stories
Session 6 Main Themes	Thoughts are not facts Negative moods effect our experience Recognising patterns of thoughts can help us We can choose to work with thoughts	Change of title to ‘Symptoms as messages from the body; thoughts are not facts’ The RAIN acronym progresses here to the Inquiry and thoughts are Not facts. Freeing self from impact of fear-based thinking/imagery, sadness/loss and proliferative thinking through dis-identification with these habitual patterns of reacting. Beginning to note the possibility of responding compassionately with discernment / wisdom. Introducing self-care front and centre (remind of oxygen mask if necessary.	Themes around fight, flight and freeze came up in reaction to the thoughts. Following a 3MBS there was a loosening up of the reactivity. However, the group had already been doing this in the homework. One man with significant muscle damage to his heart has become more aware of when heart rate increases there is need to breathe harder which can in reactive mode create anxiety. In responsive mode, he was able through cutting out worry control his heart rate. This included greater acceptance of negative thoughts, like “I have a disability.” One woman had the thought that an external stressor (a former partner) re-emerging could trigger another vascular event.
Meditation Practices in Session	30 – 40-minute sitting meditation Breathing space and review discuss breathing space as first step before wider view of thoughts		

Table 4.1 cont.

MBCT-HeLM manual development: MBCT outline, adaptations and case Illustrations

Session	MBCT for prevention of depressive relapse	Adaptations through piloting	Individual stories
Session 6 Other Exercises in Session	Practice Review Home Practice Review. Preparation for end of course Moods, thoughts and alternative viewpoints exercise.	Building on the body diagram to differentiate reactivity (proliferation) and responsiveness.	
Home Practice	Practice with a selection from series 2 tapes for 40 minutes a day 3 stage breathing space (regular) 3 stage breathing space (responsive)	For 30 minutes a day	
Session 7 Main Themes	Taking care of oneself Recognising the warning signs of depression Ways of Responding	The same themes work well here, but with greater emphasis on recognising warning signs of stress as well as low mood. Ways of responding and taking care of oneself remain equally important.	People commented on how there was a real shift in their way of being, especially in relationship to the body. A man with a very ruminative mind talked about how this mind state could make every activity depleting, whereas in a mindful state every activity can be nourishing. A real sense of care within the group. Emerging sense of permission to take care of oneself. "Working and working didn't do me any good, in fact it led to a heart attack." Choices starting to emerge, even in very stressful situations.

Table 4.1 cont.

MBCT-HeLM manual development: MBCT outline, adaptations and case Illustrations

Session	MBCT for prevention of depressive relapse	Adaptations through piloting	Individual stories
Session 7 Meditation Practices in Session	30 – 40-minute sitting meditation – awareness of breath and body 3 stage breathing space or mindful walking		
Other Exercises in Session	Practice review Home Practice Review Exercise to explore links between activity and mood Generate list of pleasure and mastery activities – plan how to best schedule such activities Identifying relapse signatures 3-stage breathing space as the first ‘step’ before choosing whether to take mindful action	Shift to taking care of oneself physically and mentally, rather than mood. Explore what nourishment feels like in the body. Responsiveness exercise with dyadic work and walking developed this experientially. Relapse signature replaced with the body diagram, mapping out responsiveness (as opposed to reactivity).	

Table 4.1 cont.

MBCT-HeLM manual development: MBCT outline, adaptations and case Illustrations

Session	MBCT for prevention of depressive relapse	Adaptations through piloting	Individual stories
Home Practice	<p>Select from all of the different forms of practice, a pattern you intend to use on a regular basis</p> <p>3-stage breathing space (regular)</p> <p>3-stage breathing space (coping)</p> <p>Develop early warning system for detecting relapse</p> <p>Develop action plan to be used in the face of lowered moods</p>	<p>Completion of responsive side of the body diagram.</p> <p>Self-care plan</p>	
Session 8 Main Themes	<p>Maintaining a balance in life is helped by regular mindfulness practice.</p> <p>Supporting intentions – linking practice to positive outcomes</p> <p>How to keep up momentum and discipline</p>	<p>Building any physical care (medication, exercise) integrally into self-care plan.</p>	<p>Real sense of group cohesion, because of a real sense of common humanity among people with similar concerns and human need to connect with others. Facilitated by pair work.</p> <p>Man with very ruminative, "in his head" cognitive style noticed in the body scan his heart beat for the first time.</p>

Table 4.1 cont.

MBCT-HeLM manual development: MBCT outline, adaptations and case Illustrations

Session	MBCT for prevention of depressive relapse	Adaptations through piloting	Individual stories
Session 8 Main theme			<p>Woman with stroke was able to notice symptoms of stroke with equanimity and being to respond to these with a sense of care.</p> <p>Generally, there was a sense of people being more aware of body sensations.</p> <p>One man described a real sense of vulnerability.</p> <p>Self-care really enhanced for people, for example using practice tactically to help with sleep.</p> <p>Attendance has been exceptional, possibly through a real sense of commitment and the contact with people throughout recruitment and orientation.</p>
Meditation Practices in Session	Body scan practice Ending meditation		

Table 4.1 cont.

MBCT-HeLM manual development: MBCT outline, adaptations and case Illustrations

Session	MBCT for prevention of depressive relapse	Adaptations through piloting	Individual stories
Session 8 Other Exercises in Session	Practice Review Home Practice Review (including early warning systems and action plans) Check and discuss plans, and link them to positive reasons for maintaining practice Discuss how to keep up momentum and discipline in practice Review whole course	Working wisely with stress/low mood	
Home Practice	Settle with programme of practice		

Table 4.2

Demographic data of the MBCT-HeLM pilot group (n = 9)

Characteristics	Number of participants	Percentage
Age mean (SD)	58.78 (11.1)	
Gender		
Male	7	78%
Female	2	22%
Marital status		
Single	1	11%
Married	6	67%
Divorced	2	22%
Widowed	0	0%
Ethnicity		
White British/Irish	8	89%
White other	0	0%
Other ethnics groups	1	11%
Employment status		
Employed	3	33%
Unemployed	0	0%
Retired	6	67%
Type of cardiovascular disorders		
Heart conditions	8	89%
Stroke	1	11%
Hypertension	0	0%
More than one cardiovascular disorders	3	33%

Table 4.3

Means, standard deviations, Cohen's effect sizes and confidence intervals for PHQ-9, FFMQ and IPQ-Brief from baseline to post-intervention

				95% CI	
	<i>N</i>	Mean (<i>SD</i>)	Effect size	Lower	upper
PHQ-9					
Baseline	9	10.8 (4.9)			
Post-intervention		4.2 (2.9)	1.74	-1.46	3.63
FFMQ-Total					
Baseline	9	112 (12.4)			
Post-intervention		143 (20.2)	1.98	-10.1	11.1
FFMQ-Observing					
Baseline	9	22 (4.5)			
Post-intervention		28 (5.4)	1.28	-4.22	2.25
FFMQ-Describing					
Baseline	9	25 (4.9)			
Post-intervention		29 (6.7)	0.72	-3.92	3.65
FFMQ-Act with awareness					
Baseline	9	24 (6.1)			
Post-intervention		28 (4.5)	0.79	-4.78	2.15
FFMQ- Nonjudgment					
Baseline	9	28 (6.2)			
Post-intervention		32 (6.8)	0.65	-4.70	3.79
FFMQ- Nonreactive					
Baseline	9	19 (4.4)			
Post-intervention		24 (7.3)	0.88	-3.75	3.89
IPQ-Brief					
Baseline	9	41.0 (12.6)			
Post-intervention		36.1 (12.4)	0.42	-7.82	8.52

Note. N: Number of participants; SD: standard deviation; PHQ-9: Patient Health Questionnaire-9; FFMQ: Five Facet Mindfulness Questionnaire; IPQ-Brief: Illness Perception Questionnaire-Brief.

Table 4.4

Means, standard deviations, Cohen's effect sizes and confidence intervals for PHQ-9, FFMQ and IPQ-Brief from baseline to follow up

				95% CI	
	<i>N</i>	Mean (<i>SD</i>)	Effect size	Lower	upper
PHQ-9					
Baseline	7	9.7 (3.5)			
Follow up		2.0 (2.6)	2.62	0.33	4.54
FFMQ-Total					
Baseline	7	121 (14.0)			
Follow up		146 (17.1)	1.68	-11.48	12.34
FFMQ-Observing					
Baseline	7	22 (4.6)			
Follow up		29 (6.3)	1.37	-4.78	3.30
FFMQ-Describing					
Baseline	7	25 (4.4)			
Follow up		30 (5.9)	1.04	-4.30	3.33
FFMQ-Act with awareness					
Baseline	7	25 (6.5)			
Follow up		29 (5.6)	0.71	-5.53	3.44
FFMQ- Nonjudgment					
Baseline	7	29 (6.6)			
Follow up		33 (5.2)	0.73	-5.62	3.12
FFMQ- Nonreactive					
Baseline	7	19 (5.0)			
Follow up		24 (6.1)	0.97	-4.67	3.55
IPQ-Brief					
Baseline	7	40.6 (14.2)			
Follow up		32.1 (8.1)	0.76	-8.52	6.76

Note. N: Number of participants; SD: standard deviation; PHQ-9: Patient Health Questionnaire-9; FFMQ: Five Facet Mindfulness Questionnaire; IPQ-Brief: Illness Perception Questionnaire-Brief.

Table 4.5

Cut-off points of the PHQ-9 scale for the MBCT-HeLM pilot group

Participant No	PHQ-9 baseline level (score)	PHQ-9 post level (score)	PHQ-9 follow up (score)
Participant 1	Moderate	None	None
Participant 2	Moderate	None	None
Participant 3	Mild	None	None
Participant 4	None	Mild	None
Participant 5	Mild	None	-
Participant 6	Severe	Mild	-
Participant 7	Moderate	Mild	Mild
Participant 8	Moderate	None	None
Participant 9	Moderate	None	None

Note. PHQ-9: Patient Health Questionnaire-9; the cut-off points for PHQ-9 (< 5)

Table 4.6

Cut-off points of PHQ-9 scale for the MBCT-HeLM pilot group

	Post-intervention (n=9)	Follow up (n=7)
Moved into non-clinical range (recovered)	6	5
Did not show a clinically significant recovery, but moved to a less clinical range	2	1
Remained in non-clinical range	1	1

Note. PHQ-9: Patient Health Questionnaire-9

The PHQ-9 weekly changes

Participant 1. This participant had a PHQ-9 score of 14 at baseline, 0 at session eight and also at follow up

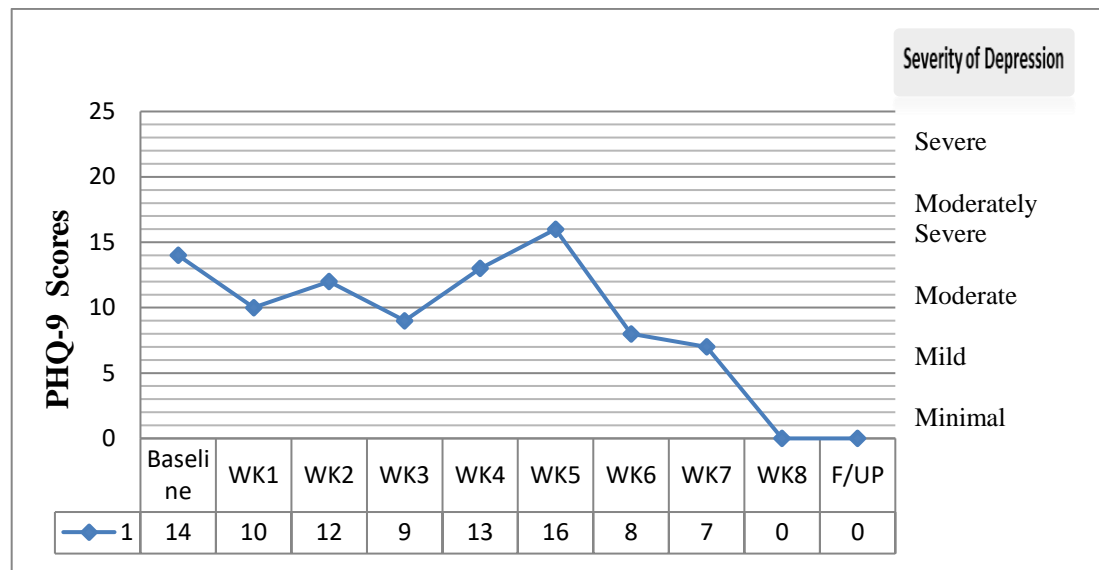


Figure 4.1. Participant 1 Scores for the PHQ-9 Depression Measure at each Time of Assessment

Participant 2. This participant had a PHQ-9 score of 11 at baseline and 2 at follow up

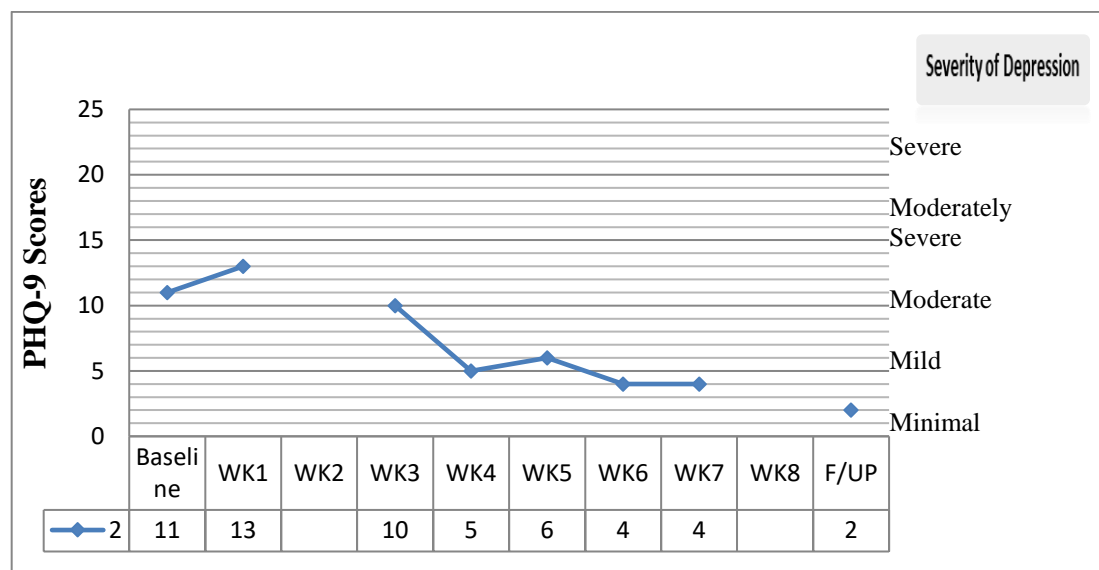


Figure 4.2. Participant 2 Scores for the PHQ-9 Depression Measure at each Time of Assessment

Participant 3. This participant had a PHQ-9 score of 6 at baseline, 0 at session eight as well as at follow up

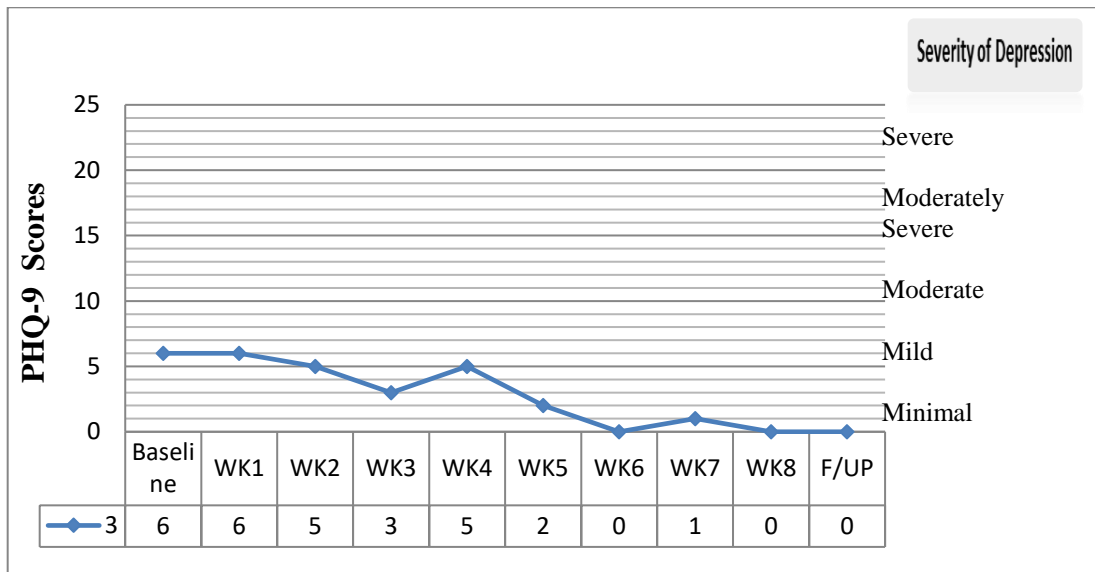


Figure 4.3. Participant 3 Scores for the PHQ-9 Depression Measure at each Time of Assessment

Participant 4. This participant had a PHQ-9 score of 4 at baseline, 5 at session eight and 0 at follow up

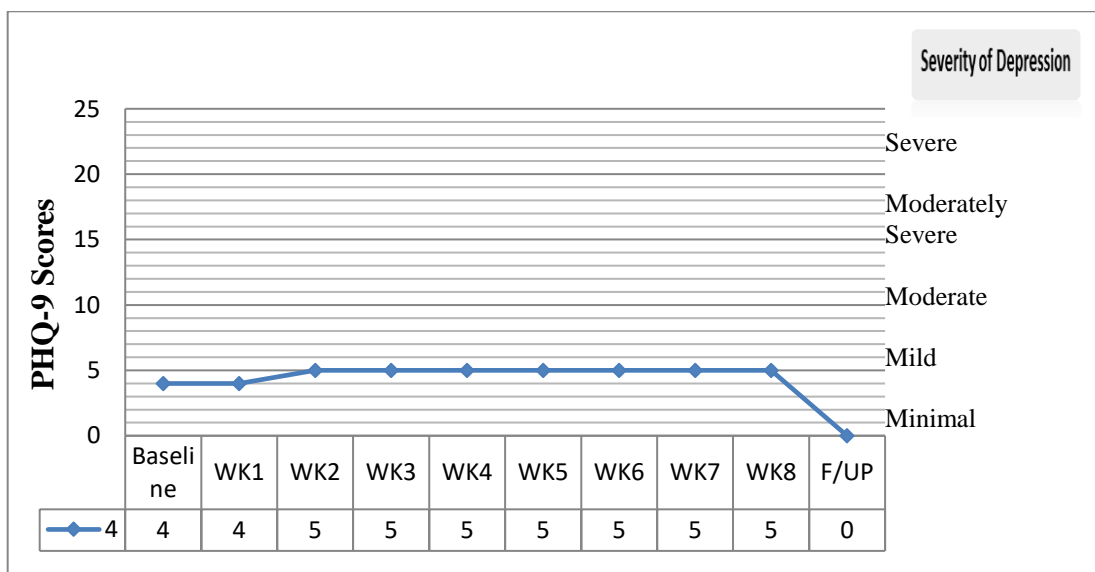


Figure 4.4. Participant 4 Scores for the PHQ-9 Depression Measure at each Time of Assessment

Participant 5. This participant had a PHQ-9 score of 8 at baseline and 3 at session eight, but did not complete the follow up

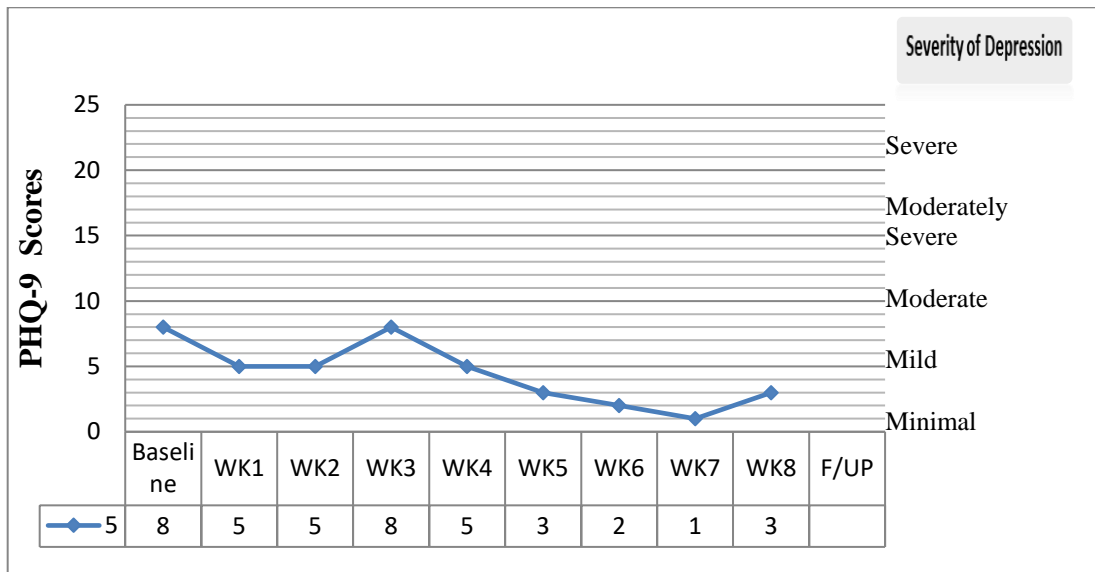


Figure 4.5. Participant 5 Scores for the PHQ-9 Depression Measure at each Time of Assessment

Participant 6. This participant had a PHQ-9 score of 21 at baseline and 9 at session seven

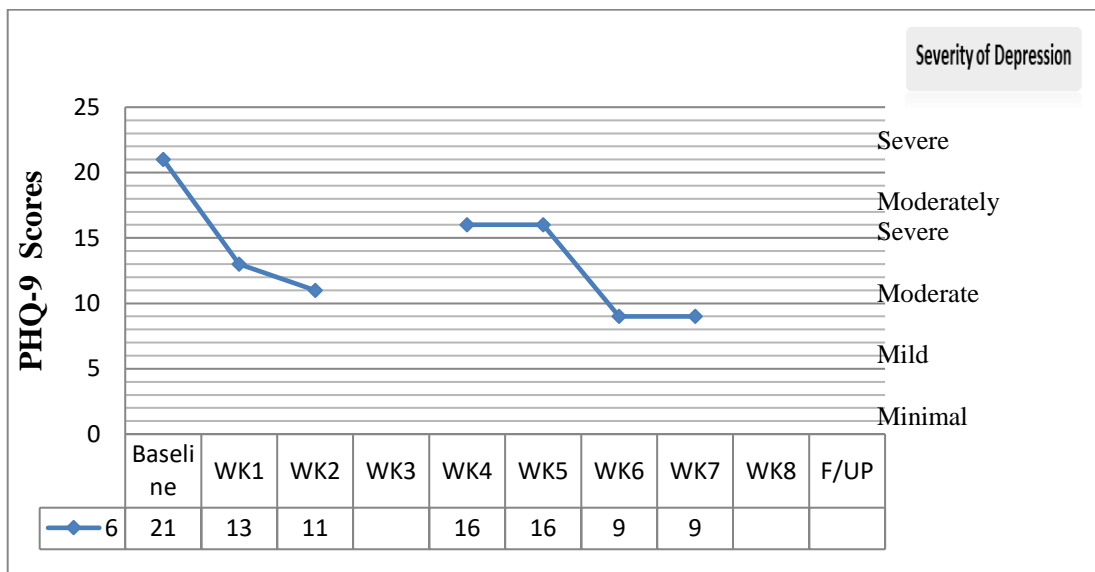


Figure 4.6. Participant 6 Scores for the PHQ-9 Depression Measure at each Time of Assessment

Participant 7. This participant had a PHQ-9 score of 10 at baseline, 7 at session eight and also, at follow up

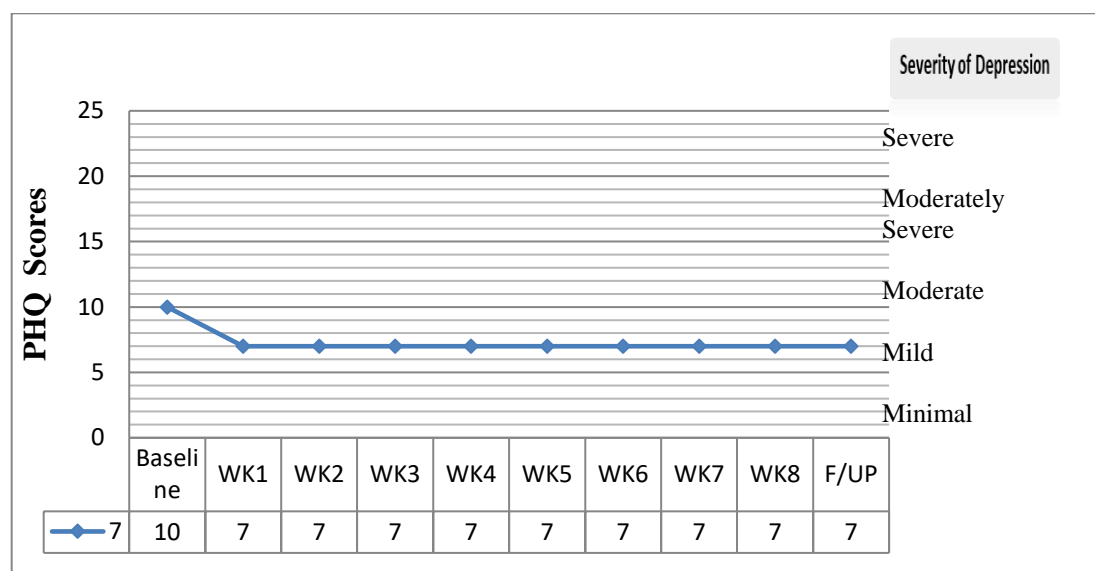


Figure 4.7. Participant 7 Scores for the PHQ-9 Depression Measure at each Time of Assessment

Participant 8. This participant had a PHQ-9 score of 12 at baseline and 4 at follow up

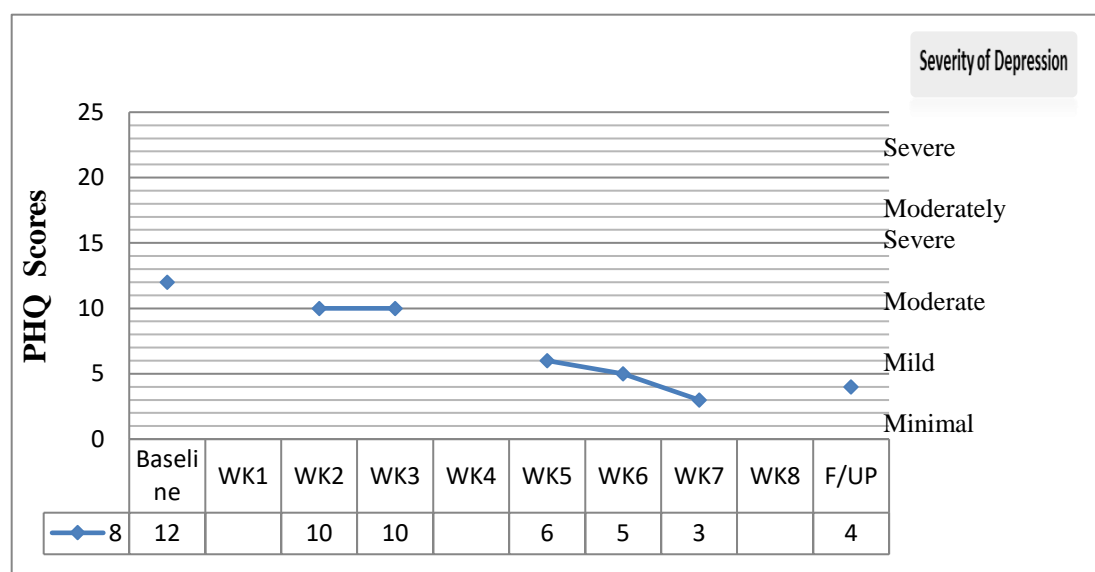


Figure 4.8. Participant 8 Scores for the PHQ-9 Depression Measure at each Time of Assessment

Participant 9. This participant had a PHQ-9 score of 11 at baseline and 1 at session eight

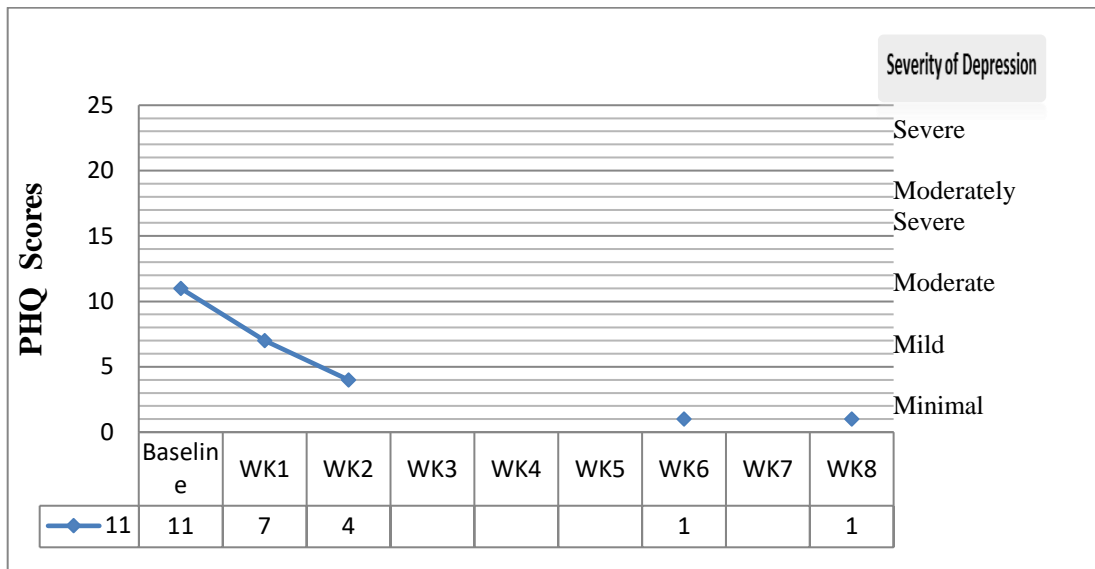


Figure 4.9. Participant 9 Scores for the PHQ-9 Depression Measure at each Time of Assessment

The FFMQ weekly changes

Participant 1. This participant had a total score of 106 on the FFMQ at baseline, 138 at the post group and 140 at the three-month follow-up

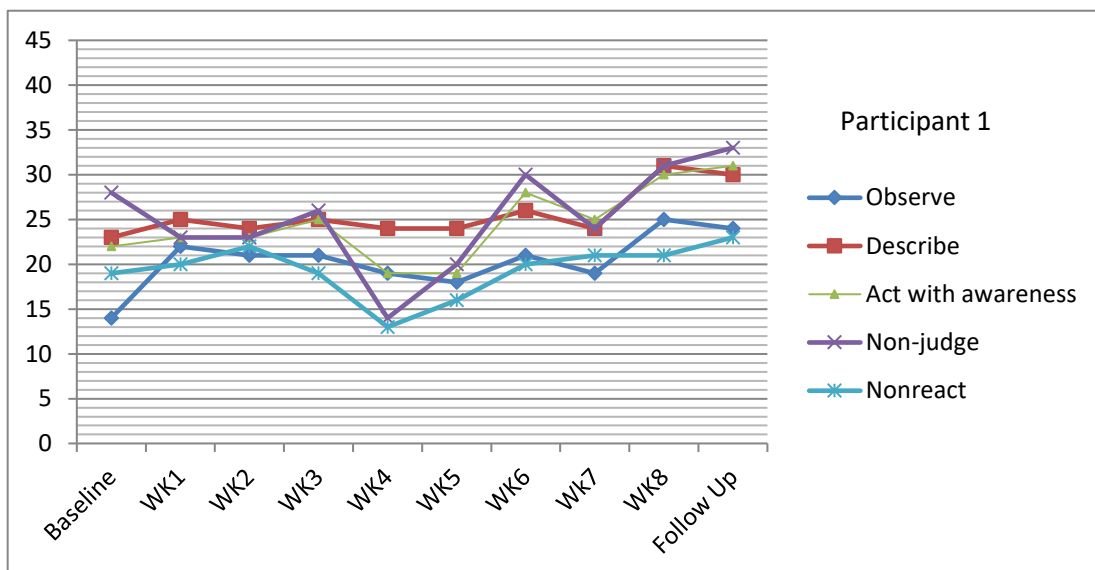


Figure 4.10. Participant 1 Scores for the FFMQ Mindfulness Measure at each Time of Assessment

Participant 2. This participant had a total score of 98 on the FFMQ at baseline and 167 at the three-month follow-up

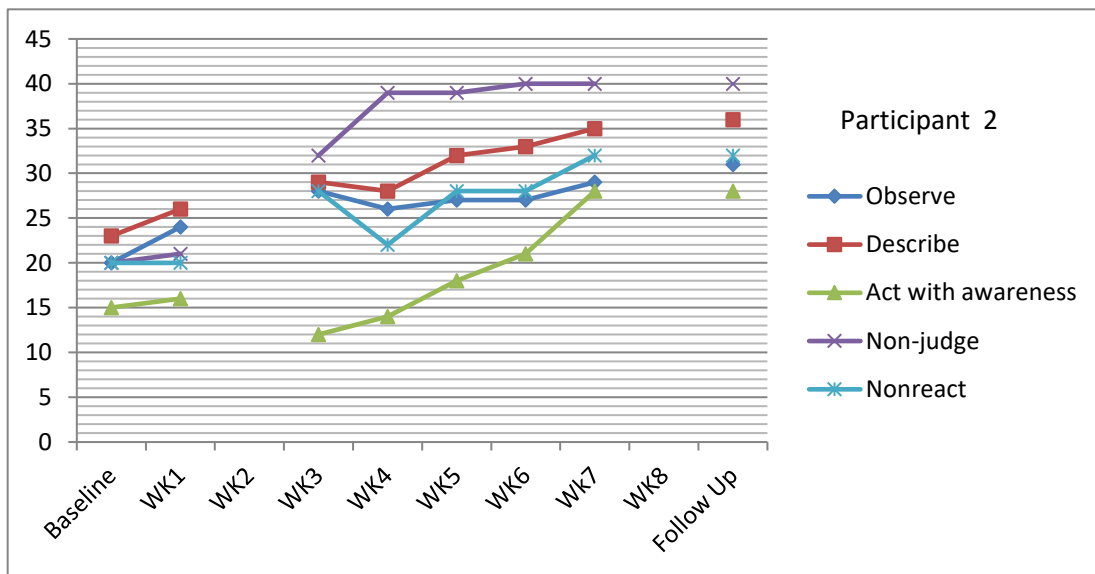


Figure 4.11. Participant 2 Scores for the FFMQ Mindfulness Measure at each Time of Assessment

Participant 3. This participant had a total score of 127 on the FFMQ at baseline, 144 at the post group and 146 at the three-month follow-up

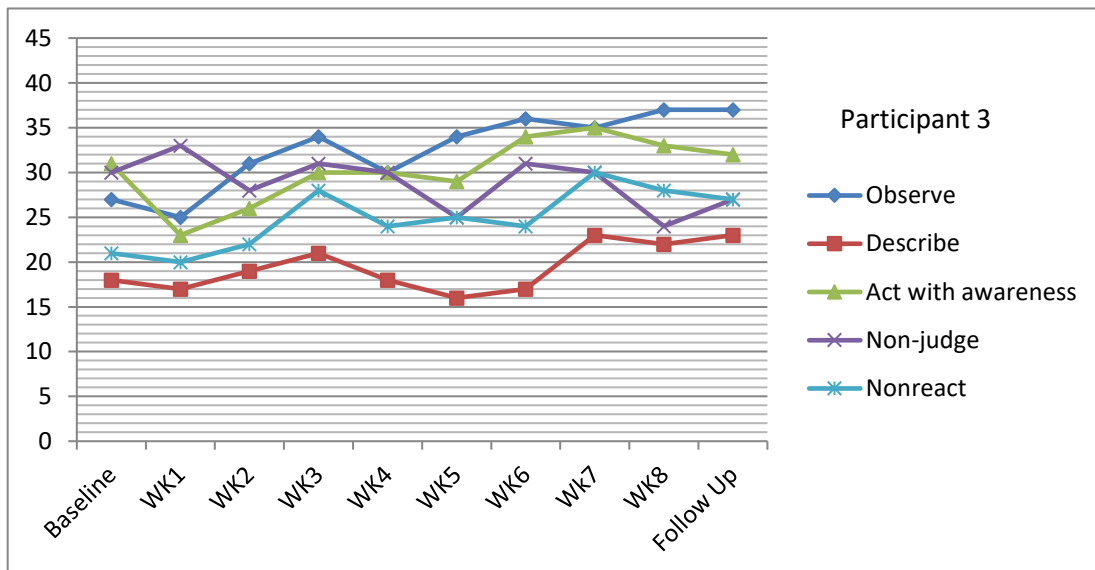


Figure 4.12. Participant 3 Scores for the FFMQ Mindfulness Measure at each Time of Assessment

Participant 4. This participant had a total score of 131 on the FFMQ at baseline, 134 at the post group and 144 at the three-month follow-up

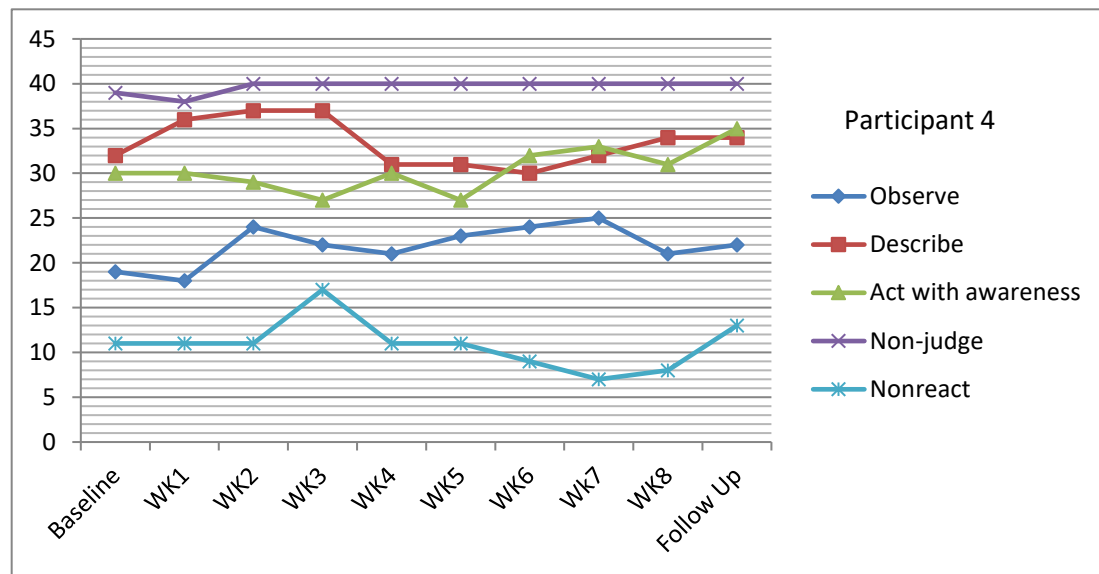


Figure 4.13. Participant 4 Scores for the FFMQ Mindfulness Measure at each Time of Assessment

Participant 5. This participant had a total score of 122 on the FFMQ at baseline, 158 at the post group

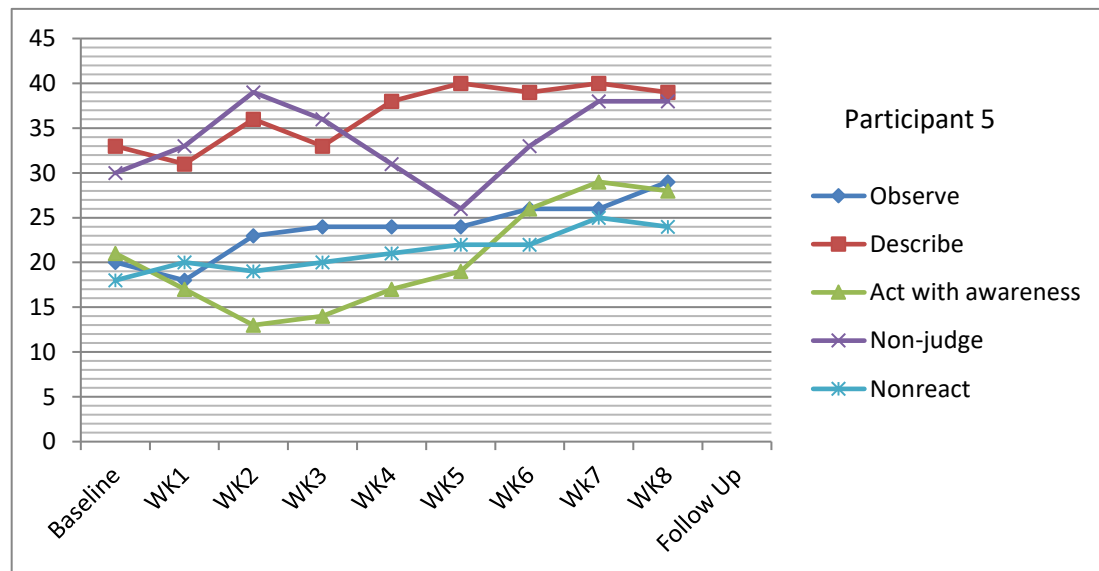


Figure 4.14. Participant 5 Scores for the FFMQ Mindfulness Measure at each Time of Assessment

Participant 6. This participant had a total score of 109 on the FFMQ at baseline and 121 at session 7

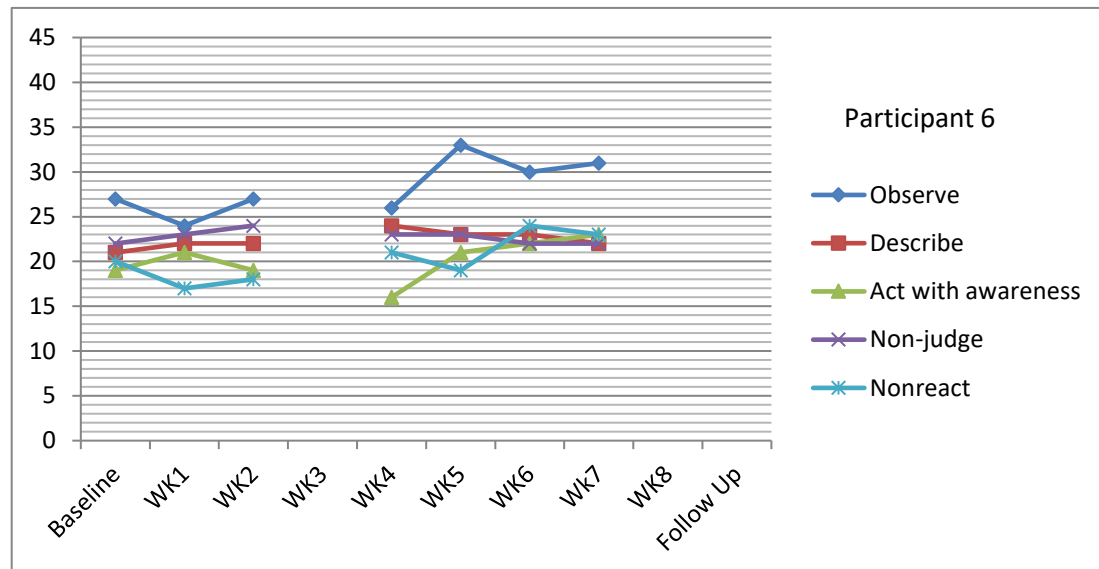


Figure 4.15. Participant 6 Scores for the FFMQ Mindfulness Measure at each Time of Assessment

Participant 7. This participant had a total score of 133 on the FFMQ at baseline, 124 at the post group and 121 at the three-month follow-up

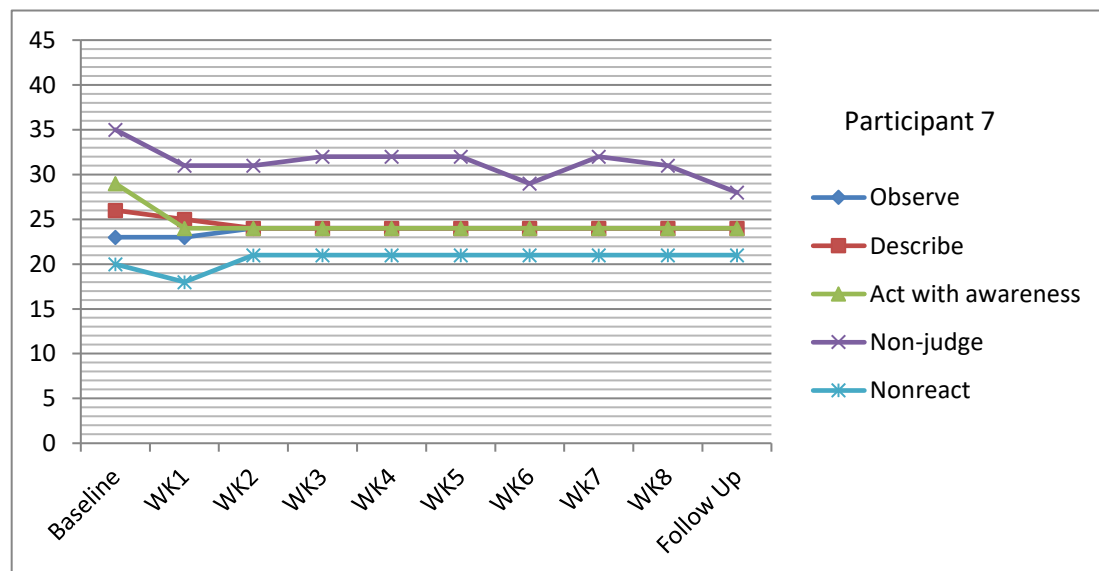


Figure 4.16. Participant 7 Scores for the FFMQ Mindfulness Measure at each Time of Assessment

Participant 8. This participant had a total score of 122 on the FFMQ at baseline, 133 at the post group and 133 at the three-month follow-up

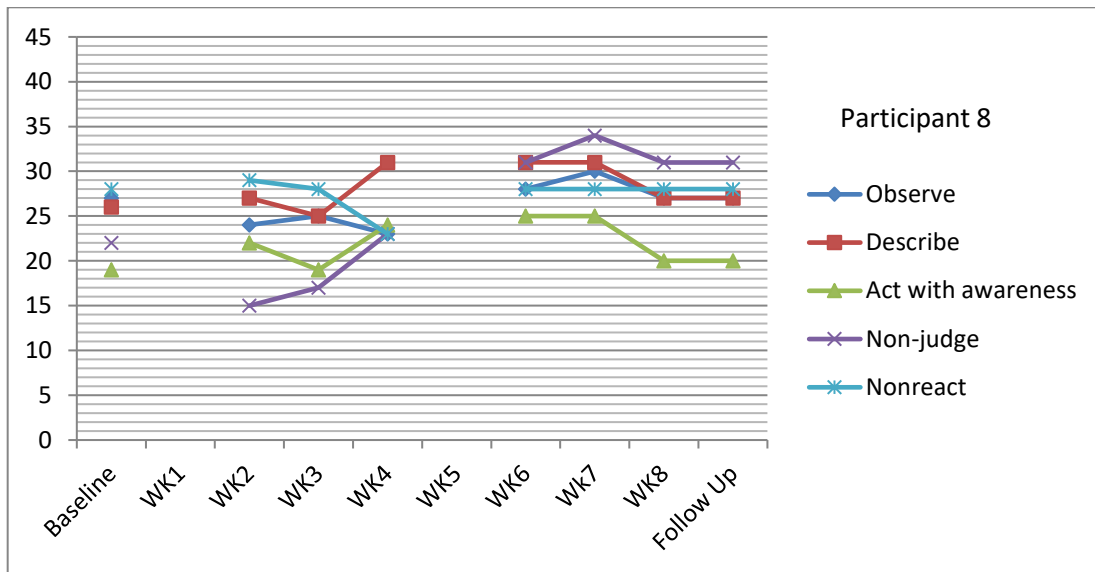


Figure 4.17. Participant 8 Scores for the FFMQ Mindfulness Measure at each Time of Assessment

Participant 9. This participant had a total score of 129 on the FFMQ at baseline, 168 at the post group and 168 at the three-month follow-up

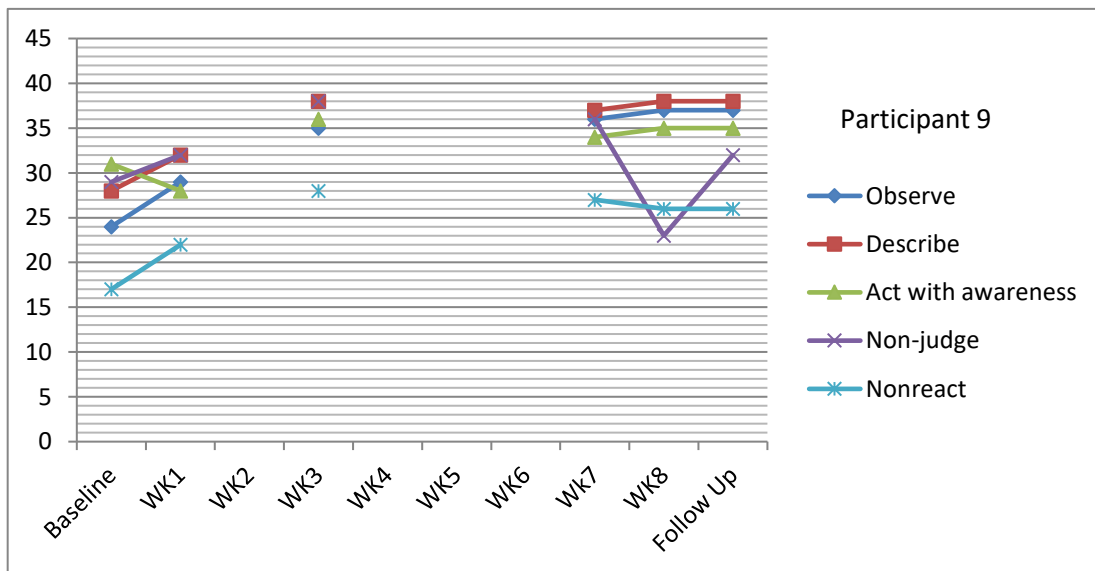


Figure 4.18. Participant 9 Scores for the FFMQ Mindfulness Measure at each Time of Assessment

The IPQ-Brief weekly changes

Participant 1. This participant had a total score of 54 on the IPQ-Brief at baseline, 45 at the post group and 31 at the three-month follow-up

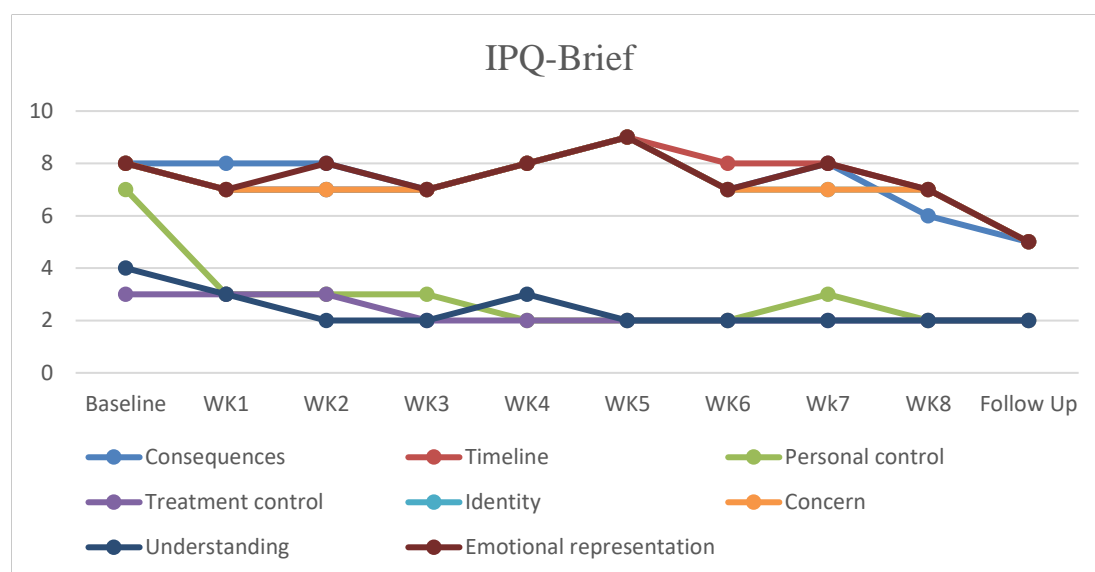


Figure 4.19. Participant 1 Scores for the Illness Perceptions Measure (IPQ-Brief) at each Time of Assessment

Participant 2. This participant had a total score of 62 on the IPQ-Brief at baseline, 51 at the post group and 39 at the three-month follow-up

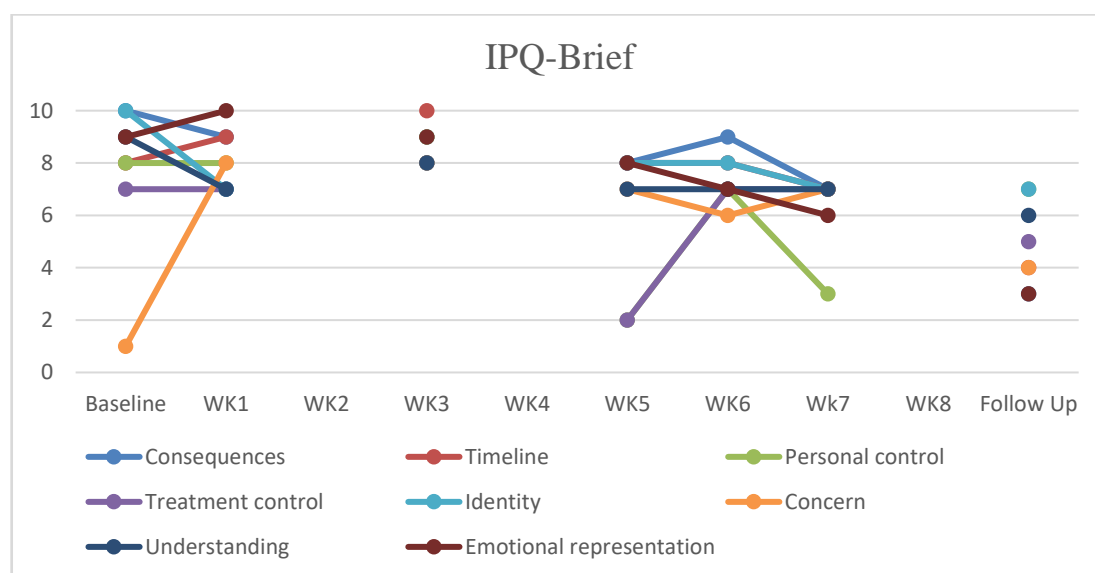


Figure 4.20. Participant 2 Scores for the Illness Perceptions Measure (IPQ-Brief) at each Time of Assessment

Participant 3. This participant had a total score of 21 on the IPQ-Brief at baseline, 23 at the post group and 29 at the three-month follow-up

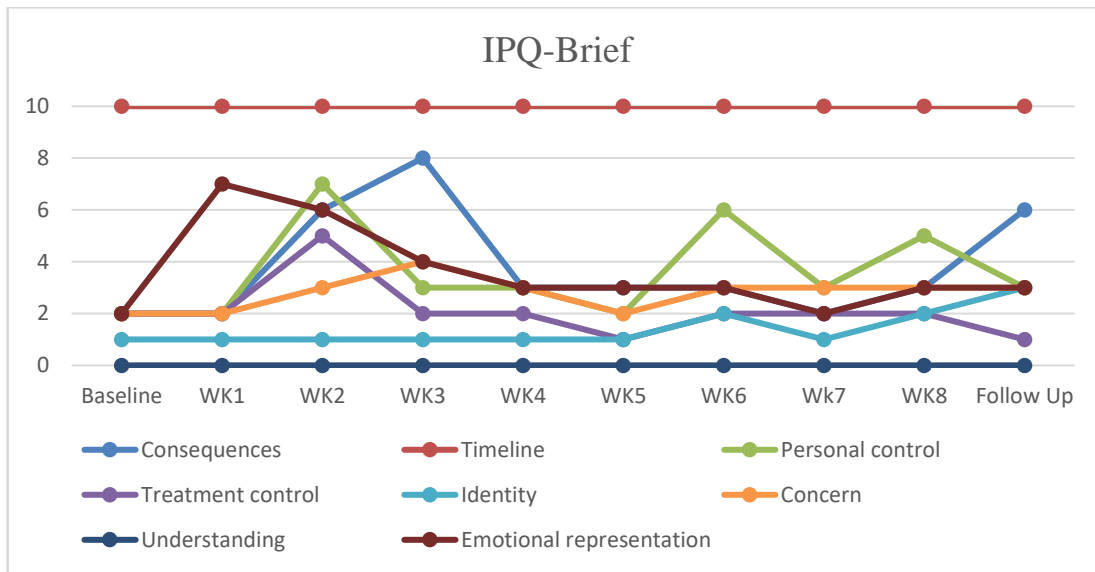


Figure 4.21. Participant 3 Scores for the Illness Perceptions Measure (IPQ-Brief) at each Time of Assessment

Participant 4. This participant had a total score of 32 on the IPQ-Brief at baseline, 24 at the post group and 27 at the three-month follow-up

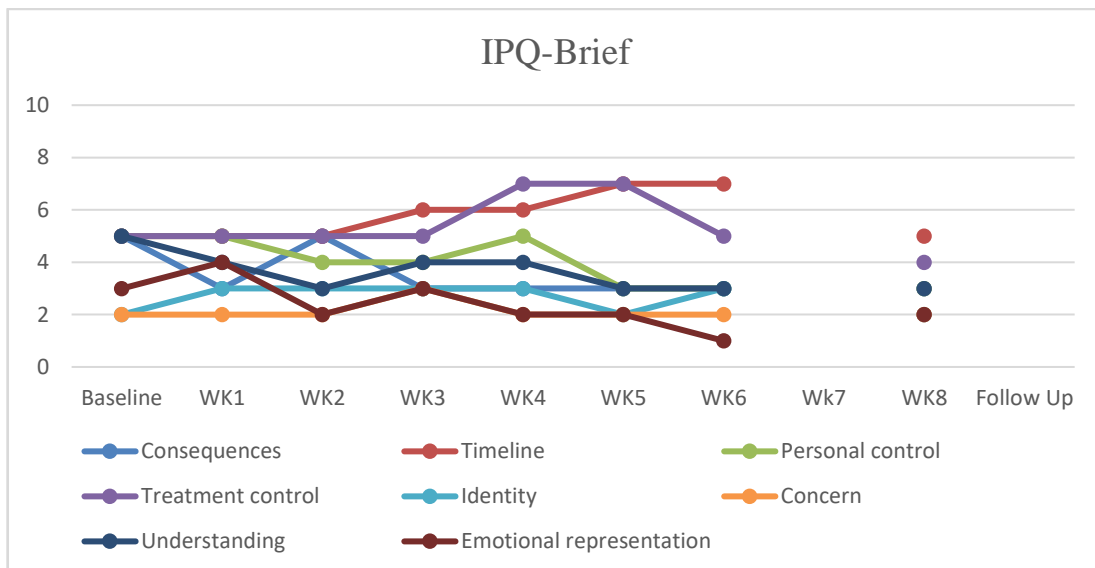


Figure 4.22. Participant 4 Scores for the Illness Perceptions Measure (IPQ-Brief) at each Time of Assessment

Participant 5. This participant had a total score of 37 on the IPQ-Brief at baseline, 29 at the post group

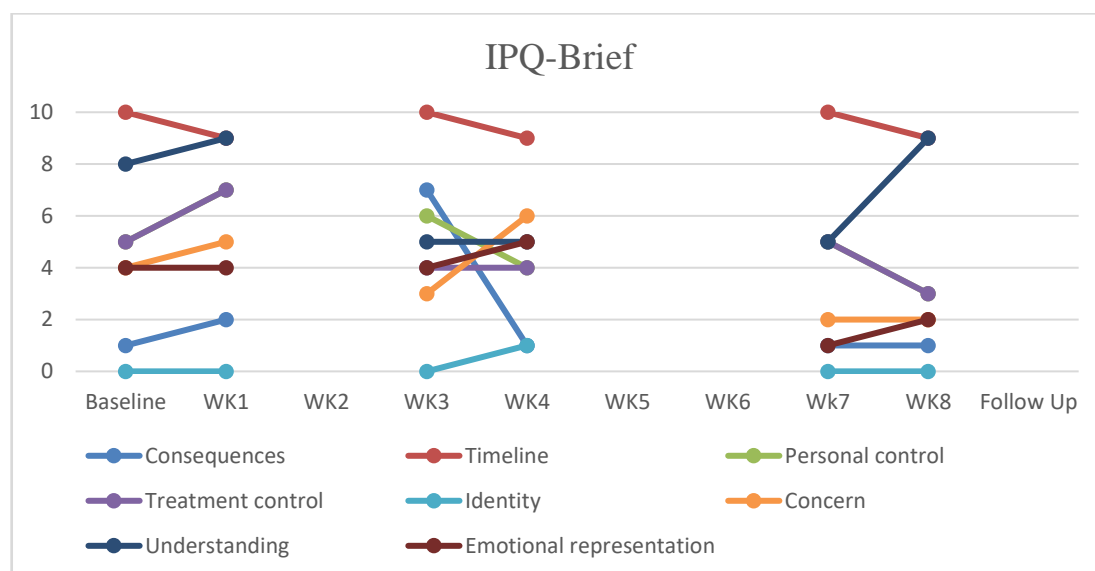


Figure 4.23. Participant 5 Scores for the Illness Perceptions Measure (IPQ-Brief) at each Time of Assessment

Participant 6. This participant had a total score of 48 on the IPQ-Brief at baseline, 46 at the post group

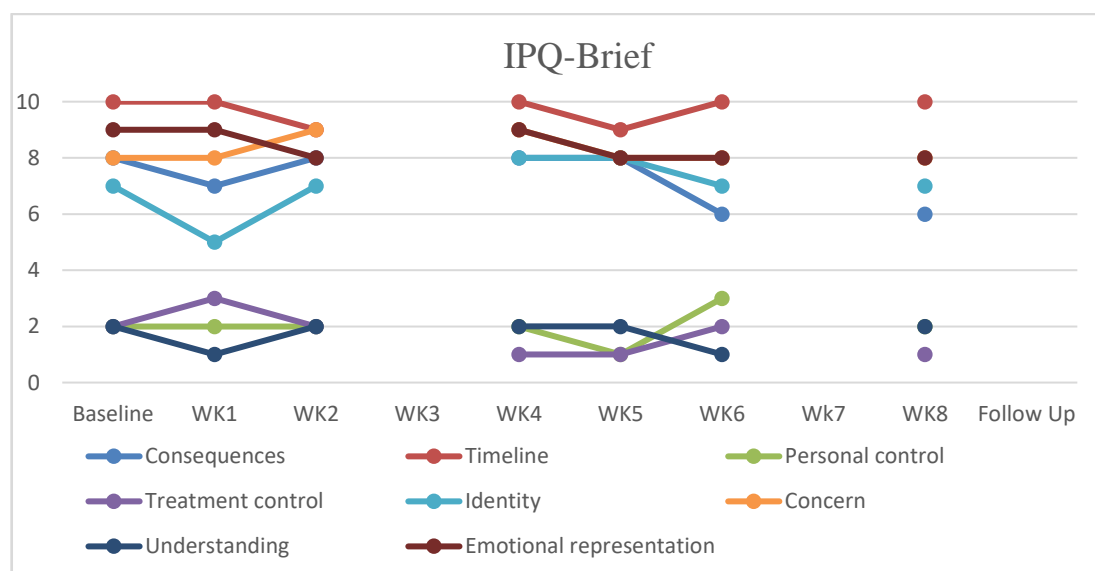


Figure 4.24. Participant 6 Scores for the Illness Perceptions Measure (IPQ-Brief) at each Time of Assessment

Participant 7. This participant had a total score of 36 on the IPQ-Brief at baseline, 45 at the post group and 46 at the three-month follow-up

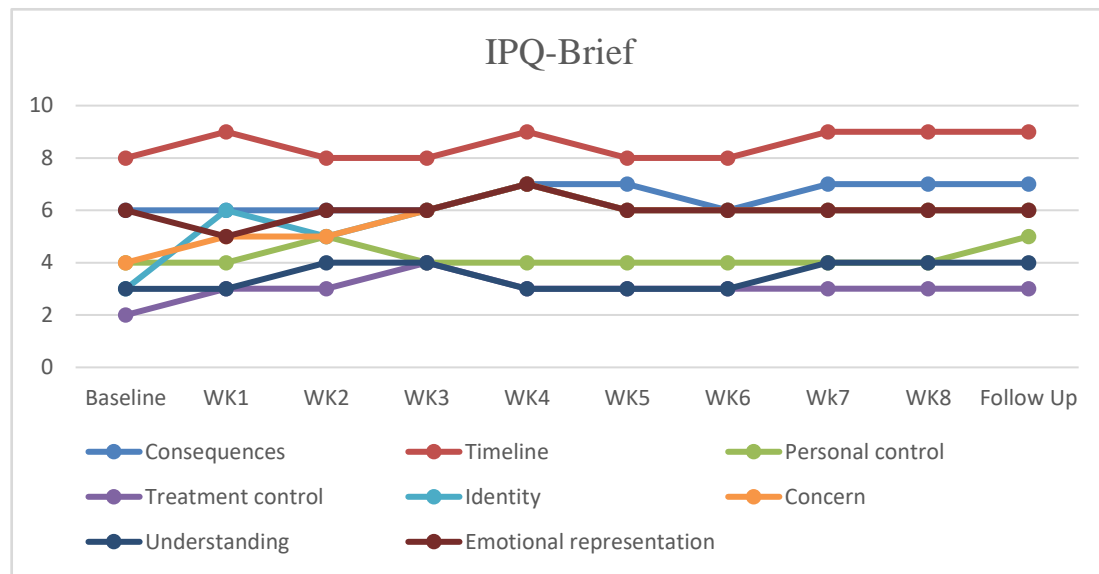


Figure 4.25. Participant 7 Scores for the Illness Perceptions Measure (IPQ-Brief) at each Time of Assessment

Participant 8. This participant had a total score of 33 on the IPQ-Brief at baseline, 18 at the post group and 21 at the three-month follow-up.

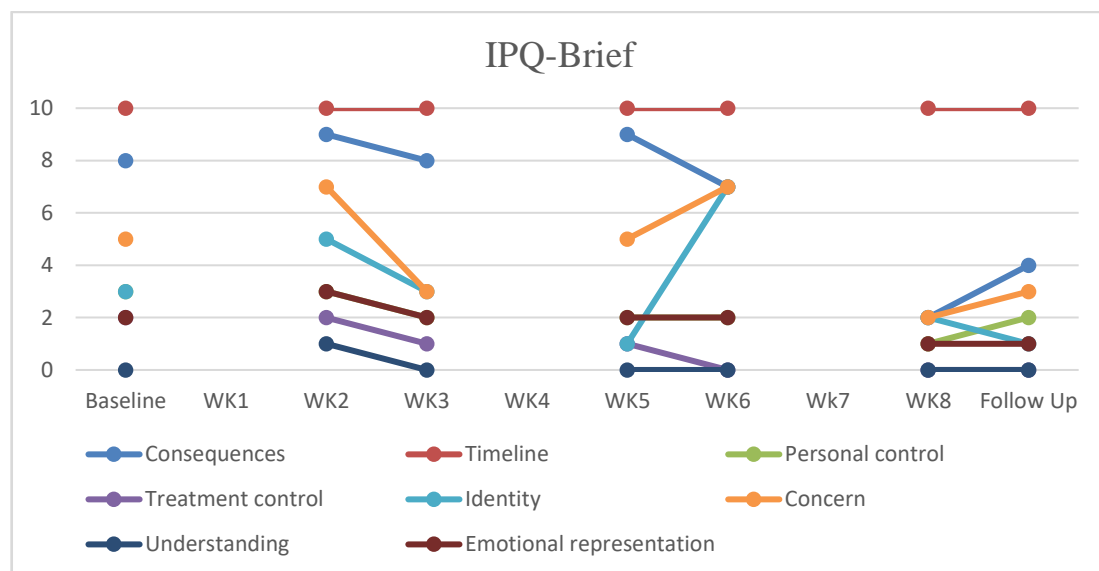


Figure 4.26. Participant 8 Scores for the Illness Perceptions Measure (IPQ-Brief) at each Time of Assessment

Participant 9. This participant had a total score of 46 on the IPQ-Brief at baseline, 44 at the post group and 32 at the three- month follow-up

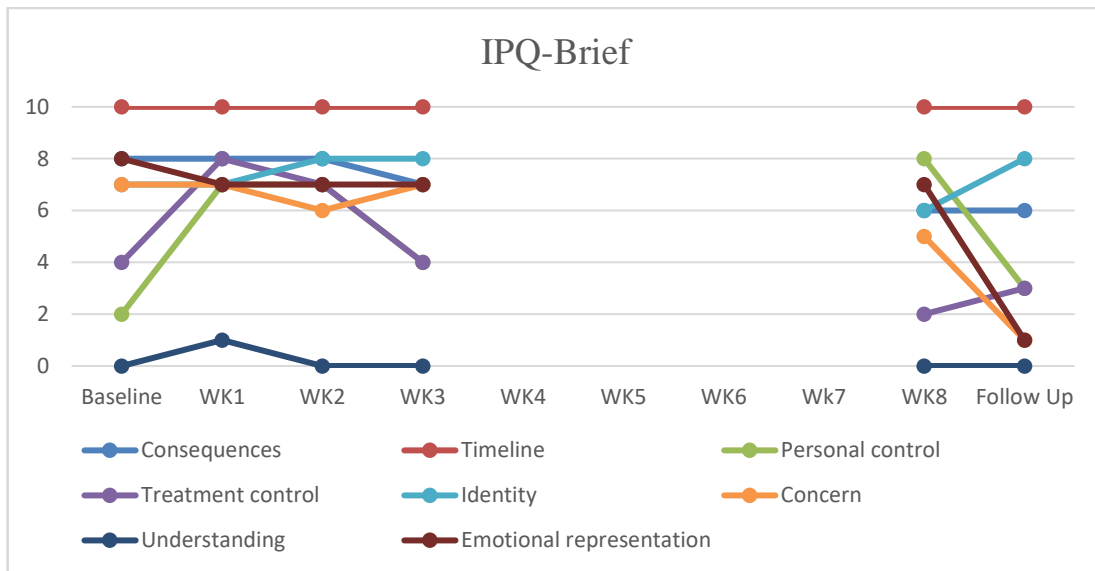


Figure 4.27. Participant 9 Scores for the Illness Perceptions Measure (IPQ-Brief) at each Time of Assessment

Chapter 5.0

Study 4

Feasibility and Acceptability of Mindfulness-Based Cognitive Therapy in People with Depression and Cardiovascular Disorders: A Three-arm Randomised Controlled Trial (Mindfulness, Special issue, 2018)

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Conflict of interest

WK is Director of the Oxford Mindfulness Centre and until 2015 was an unpaid Director of the Mindfulness Network Community Interest Company. He is the Principal Investigator of several externally funded projects evaluating the efficacy of MBCT. AE is co-director of the Mindfulness Network Community Interest Company and teaches nationally on MBCT. The other authors declare that they have no conflict interest.

Authors' contributions

MA drafted the study protocol, prepared the study materials, applied for ethics and NHS R&D approval, conducted the assessments and acceptability interviews, analysed the data and drafted the manuscript. WK participated in the design of the study, monitoring it and revision of the manuscript. CD contributed to the study design and commented on the manuscript. BD contributed to the study design and revised the manuscript. OU calculated the sample size, reviewed the statistical analysis and the manuscript. AE conducted the MBCT-HeLM and MBSR groups and commented on the manuscript. All authors read and approved the final manuscript.

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5.1 Abstract

Background: Depression co-occurs in 20 % of people with cardiovascular disorders, can persist for years, and predicts worse physical health outcomes. While psychosocial treatments have been shown to treat acute depression effectively in those with comorbid cardiovascular disorders, to date, there has been no evaluation of approaches aiming to prevent relapse and treat residual depression symptoms in this group. Consequently, the current study aimed to examine the feasibility and acceptability of a randomised controlled trial design evaluating an adapted version of mindfulness-based cognitive therapy (MBCT) designed specifically for people with co-morbid depression and cardiovascular disorders. **Methods:** A 3-arm feasibility randomised controlled trial was conducted, comparing MBCT adapted for people with cardiovascular disorders plus treatment as usual (TAU), mindfulness-based stress reduction (MBSR) plus TAU, and TAU alone. Participants completed a set of self-report measures of depression severity, anxiety, quality of life, illness perceptions, mindfulness, self-compassion and affect and had their blood pressure taken immediately before, after, and three months following the intervention. Those in the adapted-MBCT arm additionally underwent a qualitative interview to gather their views about the adapted intervention. **Results:** 3,400 potentially eligible participants were approached when attending an outpatient appointment at a cardiology clinic or via a GP letter following a case note search. 242 (7.1 %) were interested in taking part, 59 (1.7 %) were screened as being suitable, and 33 (<1 %) were eventually randomised to the three groups. Of 11 participants randomised to adapted MBCT, seven completed the full course, levels of home mindfulness practice were high, and positive qualitative feedback about the intervention was given. Twenty-nine out of 33 randomised participants completed all the

assessment measures at all three-time points. The means PHQ-9 scores for the MBCT-HeLM group were lower at post-intervention and at the three-month follow-up compared to the MBSR and TAU groups. The sample was heterogeneous in terms of whether they reported current depression or had a history of depression and the time since the onset of cardiovascular disease (one to 25 years). **Conclusions:** The adapted MBCT intervention was feasible and acceptable to participants, however, certain aspects of the trial design were not. In particular, low recruitment rates were achieved and there was a high withdrawal rate between screening and randomisation. Moreover, the heterogeneity in the sample was high, meaning the adapted intervention was unlikely to be well tailored to all the participants needs. This suggests that if the decision is made to move to a definitive trial, study recruitment procedures will need to be revised to recruit a target sample that optimally matches the adapted intervention.

Keywords: MBCT, depression, cardiovascular disorders, feasibility, acceptability

5.2 Background

Depression occurs in approximately 20 % of people with cardiovascular disorders (CVDs) (Davidson, 2012; Huffman, Celano, Beach, Motiwala, & Januzzi, 2013), often running a chronic and/or recurrent course; being associated with significant functional impairment in its own right and predicting worse medical outcomes (Baumeister, Haschke, Munzinger, Hutter, & Tully, 2015; Khawaja, Westermeyer, Gajwani, & Feinstein, 2009; Pelletier et al., 2015; Win et al., 2011). The comorbidity between depression and CVDs is associated with poor medication adherence and reduced physical and psychological quality of life (Dickens, Cherrington, & McGowan, 2012; Khawaja et al., 2009; Rustad, Stern, Hebert, & Musselman, 2013). Moreover, this comorbidity predicts a substantial increase in hospital admission rates and the use of health services (Baumeister et al., 2015; Guthrie et al., 2016; Naylor et al., 2012; Rustad et al., 2013). Notably, depression is often associated with an increase in essential CVD risk factors, including unhealthy behaviours, such as poor diet and smoking (Bonnet et al., 2005; Katon, 2011; Khawaja et al., 2009; Luppino et al., 2010). This comorbidity also negatively affects people self-care (Cameron et al., 2009; Holzapfel et al., 2009; Riegel et al., 2011) and leads to a greater inability to perform routine activities (Walters, Barley Mann & Phillips, 2014).

There may be underlying psycho-biological mechanisms in depression that directly exacerbate cardiovascular risk (Carlson, 2012; Naylor et al., 2012). In terms of biological factors, both depression and CVDs are associated with elevated platelet activation and inflammation (Dickens, 2015; Guarneri, Mercado & Suhr, 2009; Miller & Blackwell, 2006). On the psychological level, people with these conditions experience low self-efficacy, low self-care and negative illness perceptions (Greco et al., 2014; Loo,

Jiang, Koh, Lim, & Wang, 2016; Morgan et al., 2014; Riegel et al., 2011; Sarkar et al., 2007; Schoormans et al., 2014; Stafford, Berk, & Jackson, 2009; Tovar et al., 2015; van der Wal et al., 2016; Volz et al., 2016). In addition, perseverative negative cognitive processes (worry about the future and rumination about the past) have been associated with symptoms of depression (Nolen-Hoeksema, 1991). Rumination has been shown to increase the likelihood, severity and duration of depression (Watkins, 2008; Watkins & Teasdale, 2004). Also, these perseverative cognitive processes were found to be associated with CVDs, such as coronary heart disease and hypertension (Gerin et al., 2012; Kubzansky et al., 1997; Radstaak et al., 2011). Consequently, effective psychosocial treatments need to be developed to manage depression in this group, both to counter it and to enhance physical health outcomes.

Mindfulness-based programmes already have a proven track record in addressing both physical and mental health symptoms. Mindfulness is defined as “paying attention in a particular way: on purpose, in the present moment, and non-judgementally” (Kabat-Zinn, 1994, p. 4). Mindfulness-based programmes are based on some common, essential features, including a shared model of human experience, which addresses the causes of human distress and pathways to relieving it, and the centrality of mindfulness practice as an experiential inquiry-based learning process. However, different programmes have somewhat different emphases, depending on their specific intentions, the target contexts and populations (Crane et al., 2017).

Mindfulness-Based Stress Reduction (MBSR) has been used since 1979 to help relieve pain and distress in people with chronic health problems (Kabat-Zinn, 1990, 2013). Mindfulness-Based Cognitive Therapy (MBCT), which combines meditation exercises and certain cognitive therapy techniques, was developed to target negative

thinking styles in individuals with a history of depression who are at a high risk of depressive relapse and recurrence (Segal, Williams & Teasdale, 2002, 2013).

Both MBCT and MBSR were developed as approaches to develop “a new relationship” with experience characterised by present moment focus, decentring and an approach orientation” (Crane et al., 2017). They constitute a range of formal mindfulness practices as a key method for training attentional control as well as the non-judgemental attitudinal dimensions of mindfulness (Crane et al., 2017). During MBSR, people are exposed to core mental exercises that focus on breathing and body scanning along with movement exercises that concentrate on bodily sensations.

MBCT helps people to understand what factors make them vulnerable to depression recurring (based on a cognitive science account of depressive relapse) and introduces cognitive, behavioural and meditation strategies to manage these vulnerabilities. MBCT releases the mind from habitual patterns that undermine coping and lead to anxiety and depression (Kuyken et al., 2010), thus facilitating more resilient responses to challenges. Also, it enables perseverative cognitions, such as worry and rumination, to be recognised and responded to in a “decentred” way. MBCT addresses both universal vulnerabilities addressed by any mindfulness-based intervention and specific vulnerabilities implicated in depressive relapse (Crane et al., 2017). MBCT is based on psychological models of mechanisms that maintain and exacerbate common psychological problems and uses behavioural, cognitive and mindfulness strategies to address these mechanisms (Kingston et al., 2007; Michalak et al., 2011; van Aalderen et al., 2012). A recent systematic review provides promising evidence that both MBSR and MBCT are effective through the hypothesised mechanisms of increasing mindfulness and supporting decentring (Alsubaie et al., 2017).

MBSR has been found to have positive effects on anxiety, worry (Hoge et al., 2013) and high blood pressure in people with cancer (Carlson, Speca, Faris, & Patel, 2007) as well as people with unmedicated hypertension (Hughes et al., 2013). However, other studies have found that MBSR did not have effects on high blood pressure in people with cancer (Blom et al., 2014; Campbell, Labelle, Bacon, Faris, & Carlson, 2012). Regarding MBCT, whilst it was originally designed as an approach to preventing depressive relapse in people at risk of depression (Kearns et al., 2015; Kuyken, Hayes, et al., 2016), it has also been evaluated in people with sub-clinical residual symptoms (Eisendrath et al., 2016) and people suffering from physical health conditions (Schoultz et al., 2015; Van Der Lee & Garssen, 2012; van Son et al., 2014). MBCT has demonstrated effects on worry, rumination, positive and negative affect, mindfulness and self-compassion (Geschwind et al., 2011; Kearns et al., 2015; Kuyken et al., 2008; van Aalderen et al., 2012). To our knowledge, there has only been one study that has examined the effects of MBCT on depression in people with coronary heart disease (CHD) (O'Doherty et al., 2015). Whilst the outcomes of this study indicated that people in the MBCT group showed improvements regarding current depression, anxiety, quality of life and illness perceptions compared to a waiting list group, the non-randomised design used precludes strong conclusions from being drawn. Moreover, limited information is provided about the adaptations made to the MBCT programme for CHD. Therefore, further research is needed. Crane et al. (2017) have argued that mindfulness-based programmes have several essential ingredients and that there are and should be, variants to accommodate particular populations and contexts.

Maximising the potential benefits of MBCT for people with comorbid depression and CVD, requires careful consideration of the mechanisms that drive psychological distress in people with CVD as well as their particular intentions and functional

limitations. In particular, standard MBCT focuses mainly on depression specific mechanisms, for example, rumination about causes, meanings and the consequences of low mood. However, people with cardiovascular disorders worry about the cardiovascular event returning or the causes, meanings and consequences of a cardiac condition (Larsen & Christenfeld, 2009; Rozanski et al., 1999). Moreover, given the nature of cardiovascular disorders, the body cannot be assumed to provide a safe, neutral anchor for mindfulness practice and a different focus may be required; attending to bodily sensations may increase anxiety by activating worries of a further cardiac event, which can increase pulse and/or heart rate. Furthermore, a number of studies have indicated that people with CVDs have low confidence regarding their ability to take care of their condition, also known as self-efficacy, and the associated impacts on their self-care, which can lead to worse medical outcomes (Greco et al., 2014; Riegel et al., 2011, 2007; Tovar et al., 2015; Volz et al., 2016). Hence, care is needed to consider how best to enhance self-efficacy.

MBCT adaptations are intended to target more specifically the specific mechanisms that drive both depression and cardiovascular disorders (e.g., rumination and worry specific to CVD, lower self-efficacy and poor self-care) as well as the general mechanisms targeted by any mindfulness-based intervention (Alsubaie et al., 2017). As a result, we hypothesise that such adaptations should enhance MBCT's acceptability and effectiveness compared with a more generic mindfulness-based intervention. One way to test this hypothesis is to compare MBCT adapted for CVD with a non-adapted mindfulness-based programme, such as MBSR. Accordingly, we designed this study with three arms: MBCT adapted for CVD plus treatment as usual (TAU), a non-adapted generic mindfulness intervention (MBSR) plus TAU and TAU alone. We hypothesised that MBCT adapted for people with cardiovascular disorders and depression would be

more acceptable and effective than MBSR and TAU. To help ensure the adaptations made to MBCT were optimally effective and likely to be implementable in practice, for our project, the Heart and Living Mindfully “HeLM”, we followed the recent UK Medical Research Council guidelines (MRC) for developing complex interventions (P. Craig et al., 2008) and the National Institutes of Health (NIH) stage model (Onken et al., 2014). First, we established the evidence base around adapting MBCT for physical health conditions by conducting two systematic reviews (Abbott et al., 2014; Alsubaie et al., 2017). Second, an MBCT manual was adapted for people with depression and cardiovascular disorders, following a co-design process with service-users and clinicians. Third, this manual was iteratively piloted with two groups of participants. The current study (Alsubaie et al., 2018) represents the final phase of the project, namely, a feasibility RCT to establish MBCT-HeLM’s feasibility¹⁵ and preliminary acceptability¹⁶.

The study objectives

1. Establishing the feasibility of conducting a large-scale randomised controlled trial of adapted-MBCT for people with depression and cardiovascular disorders, which includes:
 - a. Evaluating the recruitment methods;
 - b. Estimating the trial recruitment, eligibility and completion rates (e.g. percentage of eligible people taking part / percentage of participants completing the trial);
 - c. Evaluating the randomisation, inclusion criteria and the data collection procedures;

¹⁵ Feasibility studies are defined as those aimed at evaluating (a) the recruitment method and sample characteristics, (b) the optimisation of the data collection method and measures, (c) the acceptability of the intervention, (d) the availability of resources, and finally (e) the preliminary assessment of responses to the intervention (see Orsmond & Cohn, 2015).

¹⁶ Acceptability refers to a “multi-faceted construct that reflects the extent to which people delivering or receiving a health-care intervention consider it to be appropriate, based on the anticipated or experiential cognitive and emotional responses to the intervention” (Sekhon, Cartwright, & Francis, 2017, p. 5)

- d. Describing the data on primary and secondary outcomes using descriptive statistics;
 - e. Estimating the standard deviation for continuous outcome measures that will be used in the calculation of the sample size for the large-scale trial.
2. Establishing the acceptability of adapted-MBCT for people with depression and cardiovascular disorders.

These objectives were formed in line with the guidelines for good practice in designing, analysing and reporting pilot and feasibility studies (Lancaster, Dodd, & Williamson, 2004; Lancaster, 2015).

5.3 Method

5.3.1 Manual Development

The MBCT-HeLM manual was developed across three stages and included two pilot MBCT groups with people with CVDs. During the first stage of the manual development, seven monthly meetings were held between HeLM projects members with expertise in mindfulness interventions and people drawn from a Patient and Public Involvement (PPI) group, who had cardiovascular problems (January to July 2013). Some of the people with CVD also had co-morbid mood disorders. Through these meetings, the original MBCT manual was reviewed and the best ways to make it more appropriate for people with cardiovascular disorders were discussed in detail. For the second stage of developing the manual, a pilot group was conducted in July/Aug 2013 using the first draft of the manual. The group comprised four members of the HeLM project team (WK, CD, AE and RV) as well as people from the PPI group and eight further participants with depression and CVD. The aim in conducting this group was to identify any changes to the manual that were necessary through discussions amongst the HeLM members, PPI group and people with cardiovascular disorders on a week by week

basis throughout the course. In the third stage of developing the manual, we conducted a second pilot group in October/Nov 2014 using the MBCT manual incorporating learning from phase 2. Weekly meetings were held after each MBCT session between the therapists (WK and AE) and the lead researcher (MA) to discuss the manual.

5.3.2 Study Design

This project is a feasibility study of a three-arm randomised controlled trial comparing adapted-MBCT (HeLM) plus treatment as usual (TAU), standard mindfulness-based stress reduction (MBSR) plus TAU, and TAU alone, for the treatment of depressive symptoms in people with comorbid depression and cardiovascular disorders. The study was conducted in the AccEPT Clinic/ Mood Disorders Centre at the University of Exeter. Participants completed a set of self-report questionnaires and blood pressure was recorded at baseline, post intervention and at three-month follow-up. Those in the adapted-MBCT (HeLM) group additionally took part in a short qualitative interview after completing the course to assess the acceptability of the adapted MBCT intervention.

5.3.3 Study Participants

Eligible participants were adults aged 18 and older with a cardiovascular disorder (heart condition, stroke or hypertension). Participants also needed to have either a history of clinical depression (major depression disorder, minor depression or dysthymia) and/or current minor depression with or without anxiety symptoms. We excluded those who met the criteria for a current episode of major depression disorder. Other exclusion criteria were co-morbid diagnoses of current substance dependence or abuse, organic brain damage, current or past psychosis, persistent antisocial behaviour, persistent self-injury and formal concurrent psychotherapy. Each participant received £10 as a token of appreciation for participating in the study every time (s)he completed the assessments

with the researcher (£30 maximum per participant). The sample characteristics of the participants in the three groups are described in Table 5.1. The mean (*SD*) age was 64.8 (10.0); 58 % were male; 61 % were married; and 94 % were white British or Irish. Approximately two thirds were suffering from heart conditions, one third had had a stroke, four people had hypertension and five had two or more cardiovascular disorders. Seventy-six percent (76 %) of the participants were not receiving any antidepressant.

5.3.4 Sample Size

We calculated the sample size based on the assumptions that about 20 % of people with recent acute coronary diseases have major depression and a further 20 % have raised symptoms of depression that do not meet the diagnostic threshold. There are about 1,000 patients per year passing through the Exeter cardiology service following having experienced acute coronary diseases. The aim was to recruit for seven months and based on that we expected the following:

1. Approximately 580 patients ($7/12 \times 1000$) would pass through in that period;
2. Approximately 230 patients (40 % of the 580) would have at least mild depression;
3. Approximately 92 patients (40 % of the 230) would participate in the study;
4. Approximately 74 patients (80 % of the 92) would be followed up at 3 months (approximately 24 per group, based on running two groups for each of MBCT and MBSR).

The 580 patients with acute coronary diseases would be large enough to estimate the percentage with at least mild depression with a margin of error no greater than ± 4 percentage points, based on the width of the 95 % confidence interval. The 230 patients with mild depression would be large enough to estimate the percentages that participate with a margin of error no greater than ± 7 percentage points. The 92 trial participants would be large enough to estimate the percentage followed up at 3 months with a margin

of error no greater than ± 11 percentage points. The 74 participants that provide data at 3 months' follow-up would be large enough to estimate the standard deviation for a continuous outcome to within 20 % of the true value.

5.3.5 Recruitment

The recruitment process was conducted through three resources: primary care (GPs), specialised services (the cardiology department at Royal Devon & Exeter Hospital), and in the community in Exeter via distributed materials, with one objective being to assess the efficiency of these methods.

Physicians and nurses in the cardiology department were invited to inform in/outpatients about the study and the outpatients clinic nurses were asked to screen interested people using Patient Health Questionnaire-8 (PHQ-8). This tool contains eight of the nine items of Patient Health Questionnaire-9 (PHQ-9) designed to evaluate major depressive disorder (MDD), as defined by the criteria stated in the Diagnostic Statistical Manual of Mental Disorders-Fourth Edition (DSM-IV). This brief version of the PHQ-9 has shown good validity and reliability for a general population (Kroenke et al., 2009) as well as for people with depression and heart conditions (Pressler et al., 2011). We chose to use this version excluding the suicide ideation or attempts item, as we anticipated delivering some of these questionnaires by post and we considered that this version might be more acceptable to patients completing the assessment in the absence of any researcher or clinician on hand to respond to any immediate concerns. We also added a question to assess whether the patient had a history of depression (no specific number of episodes) either after or before cardiovascular disorder onset. If a patient had a score between 5 and 15 (minimal to moderate depression) according to PHQ-8 cut offs or had a history of depression, (s)he received a copy of a poster (see Appendix D1) containing a brief description of the study and a summary information sheet (see Appendix D2). GPs

were also invited to refer suitable patients to the study. They were asked to identify patients registered at their surgery against the study's inclusion and exclusion criteria. Following this, patients were sent letters from the GP with a summary information sheet, which informed potentially eligible people that they could contact the researcher by post using the free-envelope, telephone or e-mail. In addition, posters containing information on the study were distributed in cafés and restaurants; the posters were put on tables so potential participants could take one.

All interested people were contacted by telephone and screened after providing verbal consent. The full information sheets (see Appendix D3) were sent to all eligible people by post. Subsequently, they were invited to an initial interview with the lead researcher (MA), to have the study explained further and to ensure they met the study inclusion criteria, using the structured clinical interview for DSM-IV-TR (SCID-I) (First, Gibbon, Spitzer, & Williams, 2002) (see Appendix E). In this interview, informed written consent (see Appendix F) was obtained from all the participants and the baseline assessment was administered using questionnaires. In addition, each participant's blood pressure was measured using an automatic blood pressure monitor.

The first screen (see Appendix G1) was conducted during the first four months of the recruitment to check the inclusion/exclusion criteria of the study by MA and RV. The second (see Appendix G2) was undertaken two weeks prior to the baseline by MA. During this phase, we checked current depression in people who were found eligible in the first screen. The reason for conducting two screens was that we thought four months duration of recruitment (the period between initial recruitment and randomisation) was a relatively long period of time for checking current depression and we wanted to make sure that people still wanted to take part so as to minimise drop out post randomisation.

5.3.6 Randomisation and Blinding

Participants were randomised using sealed envelopes to conceal allocation. Blocking was used with randomly permuted block sizes in a non-systematic sequence. Randomisation of participants was stratified to ensure balance between the three trial arms based on severity of depression (based on PHQ cut-off) and type of cardiovascular disorder (heart conditions, stroke and hypertension) (see Appendix H). The randomisation process was conducted by an independent researcher after the baseline assessment. It was not possible for the lead researcher (MA) to be blind at the post-intervention and follow up assessments. Participants were informed about their allocation status by post and those in the MBCT and MBSR groups were asked to provide convenient times for meeting the mindfulness teacher (AE) for a one-hour orientation session before starting the intervention.

5.3.7 Interventions

5.3.7.1 Adapted-MBCT (HeLM).

Mindfulness-Based Cognitive Therapy (MBCT) is a programme outlined by Segal et al. (2002, 2013) and developed based on Mindfulness-Based Stress Reduction (MBSR). It comprises an individual orientation session and eight weekly 2.5-hour group sessions. MBCT entails extensive mindfulness practices as well cognitive-behavioural exercises. It is designed to help people become aware of problematic styles of thinking and reacting, to decentre from these and respond more adaptively at times of a potential depressive relapse. The MBCT-HeLM manual maintained the essential structure and content of the original MBCT manual, but the focus and themes were reoriented to those that characterise people with low mood and CVDs. For example, in the first half of the programme participants were oriented to turning towards bodily experiences associated with CVD, with curiosity, friendliness and care. Instead of an exclusive focus on

depressive thinking, the emphasis was shifted to the ways in which physical symptoms were interpreted, for example, ‘catastrophic thinking. In session 4, the focus was on how stress/low mood/anxiety relates to bodily experience in a reciprocal relationship. We used the RAIN acronym (Recognise, Allow, Inquire and thoughts are Not facts). The first stage involves recognising when distressing bodily sensations, thoughts and images and feelings arise. Over time the intention is to support an ability to decentre and disengage from problematic ways of reacting and learn to respond with greater understanding and compassion. In session 5, the title of the session was changed to ‘Softness and Strength’. In this session, the RAIN acronym progresses to participants being invited to turn towards difficulties with a sense of allowing and inquiry. In this session, the themes around fear/hyperarousal or sadness/loss are picked up more fully with a view to beginning to decentre clearly from proliferation and over-identification. In session 6, the title of the session was changed to ‘Symptoms as messages from the body; thoughts are not facts’. In this session, the RAIN acronym progresses to Inquiry and ‘thoughts are not facts.’ The intention is to recognise, allow and decentre from fear-based thinking/imagery, sadness/loss and proliferative thinking through dis-identification with these habitual patterns of reacting. This session also includes beginning to note the possibility of responding compassionately with discernment / wisdom. Throughout the programme there was a greater emphasis on mental and physical self-care. The main differences between MBCT-HeLM, standard MBCT and MBSR are presented in Table 5.2. Participants were asked to complete a daily home practice dairy six day per week, and they were given mindfulness CDs to guide this practice. They were also invited to a long-day practice after Session 6 to make sure that those in both groups were receiving the same dose of MBCT and MBSR. The participants were asked to continue with treatment as usual (their normal clinical care). After completing the study, all the MBCT-

HeLM participants were invited to regular reunion sessions in the AccEPT Clinic/ Mood Disorders Centre at the University of Exeter.

5.3.7.2 Standard MBSR.

Mindfulness-Based Stress Reduction (MBSR; Kabat-Zinn, 1990, 2013) consists of eight weekly 2.5 hours sessions with up to 30 participants and includes a full day of practice. MBSR comprises extensive formal and informal mindfulness-based exercises (e.g., body scan, breathing awareness, mindful yoga, mindful eating and mindful walking). The intention is to develop awareness and a new relationship with experience characterised by present moment focus, approach orientation, compassion, understanding and equanimity. Participants were asked to complete a daily home practice dairy six day per week, and they were given mindfulness CDs to guide this practice. They were also asked to continue with treatment as usual (their normal clinical care). After completing the study, all the MBSR participants were invited to regular reunion sessions in the AccEPT Clinic/ Mood Disorders Centre at the University of Exeter.

5.3.7.3 Treatment as usual (TAU).

In this group, the participants were asked to continue their normal clinical care. Treatment as usual (TAU) could include psychiatric treatment, outpatient consultation, routine visits to the GP and support programmes from the mental health or cardiac nurse. These participants were offered standard MBCT service AccEPT Clinic at the Mood Disorders Centre after completing the follow up assessment.

5.3.8 Assessment Time-Points

Participants were assessed at three-time points: a baseline assessment conducted three weeks prior to randomisation; a post-intervention assessment taking place at the end of the MBCT-HeLM and MBSR groups; and a three-month follow-up after the interventions completion. For the TAU group, all assessments were at the same point

post-randomisation. The lead researcher (MA) conducted all three assessments at face-to-face meetings with the participants.

5.3.9 Outcomes

5.3.9.1 Feasibility.

The feasibility of MBCT-HeLM intervention in people with depression and cardiovascular disorders was established based on recruitment (recruitment methods, screening and baseline phases), retention rate (course completion), attrition rate (dropouts), participants' adherence (attendance, home practice and assessment completion) and other procedures, including randomisation, therapist adherence, inclusion/exclusion criteria and outcome measures. The rate of recruitment was quantified by the percentage of eligible people that were recruited and randomised. Retention and attrition were assessed by determining the percentage of completers and dropouts. The participants' adherence was measured using attendance rate and total time spent on the home mindfulness practice. In terms of assessment completion, we measured the percentage of people who fully completed each outcome assessment in each of the three groups.

5.3.9.2 Acceptability.

We developed a short interview schedule with questions focusing on the MBCT-HeLM participants' overall satisfaction with the study, their views regarding the MBCT-HeLM techniques, home practice, the group format, and the physical and psychological advantages/ disadvantages from having taken part. The interviews were carried out face-to-face at the Mood Disorders Centre/University of Exeter. All the people who completed the MBCT-HeLM course were interviewed. In addition, those who dropped out were asked about their overall experience with the study and their reasons for

dropping out. Each interview was audio recorded and took between 15 and 25 minutes, being subsequently transcribed verbatim by a transcription service.

5.3.9.3 Measures.

The primary outcome was depression symptoms. Secondary outcomes were physical health related, including blood pressure, which is considered to be an important risk factor for developing a cardiovascular disorder (Kelly & Fuster, 2010) and heart-focused anxiety (HFA), which has been found to be linked to increased anxiety, depression and lower quality of life among people undergoing cardiac surgery (Hoyer et al., 2008). Further secondary outcomes, are illness perceptions (participants' beliefs about their illness), which are associated with the speed and quality of recovery after myocardial infarction (Petrie et al., 1997) and general and specific quality of life in people with cardiovascular disorders, which are considered to be important indicators of the effectiveness of any treatment in people with heart disorders (Thompson & Yu, 2003). Additionally, we used three process measures that we might use in a definitive trial to examine hypothesised mechanisms of action in MBCT-HeLM: mindfulness, self-compassion and positive and negative affect. These processes have been identified as mediators of outcome in previous studies of MBCT (Geschwind, Peeters, Drukker, van Os & Wichers, 2011; Kuyken et al., 2010; Shahar, Britton, Sbarra, Figueredo, & Bootzin, 2010). Also, mindfulness has been found to be a mediator of the effects of MBCT in people with coronary heart diseases (O'Doherty et al., 2015). See Appendix I for the measures that were used in this study.

5.3.9.4 Primary measure.

5.3.9.4.1 Depression. Depressive symptoms were assessed using Patient Health Questionnaire-9 (PHQ-9; Spitzer, Kroenke, Williams, & Group, 1999), which contains nine items reflecting Diagnostic Statistical Manual of Mental Disorders-Fourth Edition

(DSM-IV) criteria of major depression disorder (MDD). Each item is scored between 0 and 3 with, a range of total scores between 0 and 27. The cut-off points of PHQ-9 are 5, 10, 15, and 20, which define the following levels of severity: none/minimal depression (0-4), mild depression (5-9), moderate depression (10-14), moderately severe depression (15-19), and severe depression (20-27). PHQ-9 has been found to have adequate psychometric properties in the UK (Cameron et al., 2008) as well as in people with coronary heart disease (Haddad et al., 2013).

5.3.9.5 Secondary measures.

5.3.9.5.1 Blood pressure. Levels of blood pressure in each participant were recorded using an Advanced Clinically Validated Blood Pressure Arm Monitor, which provides readings of systolic and diastolic blood pressure.

5.3.9.5.2 Generalised anxiety. Severity of general anxiety symptoms was assessed using Generalised Anxiety Disorder-7 (GAD-7; Spitzer, Kroenke, Williams, & Lowe, 2006). This questionnaire comprises seven items reflecting the DSM-IV criteria of generalised anxiety disorder (GAD). Each item is rated between 0 and 3 with, a range of total scores between 0 and 21 with four levels of severity: none (0-4), mild anxiety (5-9), moderate anxiety (10-14), and severe (15-21). GAD-7 has been found to have good reliability and validity (Spitzer et al., 2006).

5.3.9.5.3 Cardiac anxiety. The Cardiac Anxiety Questionnaire (CAQ; Eifert et al., 2000) was used to assess heart-focused anxiety (HFA). The CAQ is a self-report containing 18 items reflecting three clinical aspects: cardio-protective avoidance behaviour, heart-focused attention and fears about heart sensations. Each item is scored from 0 (never) to 4 (always) with a range of total scores between 0 and 72. Higher scores indicate greater heart-focused anxiety (HFA). The CAQ has been found to have good

internal consistency (Eifert et al., 2000). In the HeLM study, this questionnaire was used with people with heart conditions only.

5.3.9.5.4 Health-related quality of life. The RAND 36-Item Health Survey 1.0 (Hays et al., 1993) was used to assess the participants' general quality of life. It contains 36 items, covering eight domains: physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (V), social functioning (SF), role-emotional (RE) and mental health (MH). These domains can be grouped into two main components: physical and psychological. Each item is recoded on a 0 to 100 range and then an average of the scores for the items in each domain is obtained, with higher scores being consonant with greater functioning and enhanced well-being. The RAND 36-Item has been found to have good psychometric properties (Hays, Sherbourne, & Mazel, 1995).

5.3.9.5.5 Health-related quality of life in people with cardiac problems. The Seattle Angina Questionnaire (SAQ; Spertus et al., 1995) is a specific measure that has been widely used to assess the health outcomes in people with angina. It contains 19 items, covering five clinical dimensions (subscales): physical limitations, angina stability, angina frequency, treatment satisfaction and disease perception. Each subscale is scored by reordering each response, summing up the scores for each subscale and then transforming the scores to a range 0-100. No actual total for SAQ could be obtained, but those with higher scores indicate high levels of health and satisfaction. The SAQ has shown good validity and reliability in the UK (Garratt, Hutchinson, & Russell, 2001). In the HeLM study, we used this questionnaire with people with heart conditions only.

5.3.9.5.6 Illness perception. The Illness Perception Questionnaire-Revised (IPQ-R; Moss-Morris et al., 2002) was used to assess participants' beliefs about their illness. This measure is a revised version of the illness perception questionnaire (IPQ) that was developed to assess cognitive representations. The IPQ-R measure comprises three

sections; the first and third sections are called identity and causality. The second section contains 38 items covering seven dimensions: timeline acute/chronic, timeline cyclical, consequences, personal control, treatment control, illness coherence and emotional representations. In the HeLM study, we used the second section with the 38 items, each being rated between 1 and 5. The IPQ-R was scored by reversing some items and then summing up scores for each of the seven dimensions. No total for IPQ-R could be obtained. The IPQ-R measure has been used with people suffering from heart diseases and has showed good psychometric properties in the UK (Moss-Morris et al., 2002).

5.3.9.6 Process measures.

5.3.9.6.1 Mindfulness. The Five-Facet Mindfulness Questionnaire (FFMQ; Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006) was designed to assess different aspects of mindfulness. It consists of 39 items, reflecting five facets: non-reactivity to inner experience (7 items), observing (8 items), acting with awareness (8 items), describing (8 items) and non-judging of experience (8 items). Each item is rated on a 5-point Likert scale ranging from 1 (never or very rarely true) to 5 (very often or always true). The questionnaire is scored by reversing some items and then summing up the scores for each of the five facets. The total FFMQ score is obtained by summing up the five facet scores. The FFMQ has been found to have good psychometric properties (Baer et al., 2006, 2008).

5.3.9.6.2 Self-compassion. The Self-Compassion Scale (SCS; Neff, 2003) is a measure assessing the overall compassion according to three components: self-kindness, common humanity and mindfulness. Each component has a negative aspect: self-judgment, isolation and over-identification, respectively. It contains 26 items that are rated on a Likert scale from 1 (almost never) to 5 (almost always). The SCS subscales are scored by calculating the mean of responses on each subscale. The total SCS is

scored by reversing scores of the negative subscales (self-judgment, isolation, and over-identification) and then computing a mean of the subscale means. The SCS has been found to have good validity and reliability across different cultures (Neff, 2003).

5.3.9.6.3 Positive and negative affect. The Positive and Negative Affect Scale (PANAS; Watson, Clark, & Tellegen, 1988) was used to assess participants' mood. It comprises 20 self-administered items that can be used to evaluate one's mood at various times-points. The items are rated using a Likert scale from 1 (very slightly) to 5 (extremely). The positive affect subscale is scored by adding the scores of items 1, 3, 5, 9, 10, 12, 14, 16, 17, and 19. The negative affect subscale is scored by adding the scores of items 2, 4, 6, 7, 8, 11, 13, 15, 18, and 20. The PANAS has shown good validity and reliability in the UK (Crawford & Henry, 2004).

5.3.10 Home Practice

The home practice record sheet was used to assess which mindfulness practice participants were completing it and the amount of time spent on practice each week. Participants in the MBCT-HeLM and MBSR groups were asked to complete this sheet each week throughout the course and return it to the mindfulness teacher. The lead researcher photocopied the sheets and they were returned to the participants the following week.

5.3.11 Structured Clinical Interview for DSM-IV-TR (SCID-I)

The Structured Clinical Interview for DSM-IV-TR (SCID-I) (First et al., 2002) was used to assess the presence of psychiatric diagnoses. In this study, we used some parts of the mood episodes section (current major depressive episode (MDE), past MDE and current dysthymic disorders) in order to assess a potential participant's eligibility in detail.

5.3.12 Therapist Adherence and Competence

Both the MBCT-HeLM and MBSR groups were conducted by a trained and experienced mindfulness-based therapist (AE) with a considerable length of practice. The therapist received weekly supervision from an independent supervisor. The group sessions were video-recorded, and an independent mindfulness therapist evaluated two MBCT and two MBSR sessions for competence and adherence. The Mindfulness-based Intervention: Teaching Assessment Criteria (MBI: TAC) (Crane et al., 2013), which is rated on a scale from 1 (incompetent) to 6 (advanced), was used (see Appendix J).

5.3.13 Statistical Analysis

The data were analysed in line with the guidelines for good practice in designing, analysing and reporting pilot and feasibility studies (Lancaster, Dodd, & Williamson, 2004; Lancaster, 2015). The percentage of eligible people that consented to participate is reported with 95 % confidence intervals. Similarly, the percentage of the participants that provided follow-up data and the percentage of those in the MBCT-HeLM and MBSR arms that completed the interventions are reported. The characteristics of the participants in each trial arm are summarised using means and standard deviations for continuous variables and percentages for categorical ones. Given the study aims were to assess the feasibility and acceptability of MBCT-HeLM, but not testing hypotheses, we report the quantitative results in a descriptive way and have not reported *P*-values. Instead, we provide 95 % confidence intervals, which illustrate the amount of uncertainty there is regarding the true intervention effect. For each of the primary and secondary outcomes, we used the means, standard deviations (SDs), mean differences and 95 % confidence intervals between the groups. For the process measures, we used a similar method of using the means, standard deviations (SDs), mean differences and 95 % confidence intervals between the groups. Regarding the qualitative analysis, the NVivo programme

was employed to help with coding the data. We used the thematic analysis method with the six phases suggested by Braun and Clarke (2006) in order to analyse the interviews (see Appendix K).

5.4 Results

The results of the study are reported according to guidelines for good practice in designing, analysing and reporting pilot and feasibility studies (Lancaster, Dodd, & Williamson, 2004; Lancaster, 2015). In addition, we used the Consolidated Standards of Reporting Trials (CONSORT) extension guidelines for reporting pilot and feasibility studies (Thabane et al., 2010).

5.4.1 The Feasibility of an RCT of MBCT-HeLM for People with Depression and CVD

The first aim of this study was to establish the feasibility of conducting a randomised controlled trial of MBCT-HeLM in addition to TAU vs. MBSR along with TAU vs. TAU alone. In general, the results indicate that there are several positive indicators about the feasibility, with the main challenge being recruitment.

5.4.1.1 Recruitment rate.

5.4.1.1.1 Recruitment methods. Three methods of recruitment (GPs, cardiology department at Royal Devon and Exeter hospital and advertisement) were used in the HeLM feasibility study. The recruitment and screening phases were conducted over four months (July to October 2014). Invitations were sent to 3,340 people through three GPs (two in Exeter and one in Exmouth), while a summary of the study was handed to 50-60 patients out of approximately 144 patients passing through the outpatients' clinic for about 12 weeks by the cardiac nurses in the cardiology department. This was different to our calculation of the sample size as we estimated that 82 patients would pass every month (250 for the 12 weeks). In addition, 600 copies of a study poster were distributed

in nine cafés and restaurants in Exeter city centre, three weeks before the recruitment ended.

5.4.1.1.2 Screening and baseline phases. As shown in the CONSORT diagram (Figure 5.1), of the 3,340 people approached through GPs, 239 people (7.1 %) were interested, 180 people (5 %) showed no interest (i.e. People who sent the reply form back to the researchers stating that they were not interested in the study) and the remainder (88 %) did not respond to the letters (i.e. People who did not send the reply form back to the researchers). Regarding the cardiology department, we had three interested people (5 % of the 60 people who were approached through the cardiology department) and no individuals responded to the advertisements. During the first screen, 183 out of the 242-interested people (76 %) were excluded for the following reasons: no low mood as people reported ($n = 99$), no cardiovascular disorder ($n = 20$), not interested anymore ($n = 15$), could not attend the group dates ($n = 20$), non-contactable ($n = 12$) and other reasons ($n = 17$). This resulted in 59 out of the 3,340-approached people (1.7 %) meeting the criteria of the first screen. For the second screen, two people were excluded, as they had current major depression, another one was non-contactable and 15 did not wish to continue the study. The reasons for withdrawing were health ($n = 8$), family ($n = 2$), work ($n = 3$), or holding the view that the mindfulness course did not seem right for them ($n = 2$). In the baseline phase, 41 people who met the study criteria were invited to a diagnostic interview where the SCID was applied to check for past and current major depressive disorder (MDD), minor depression as well as dysthymia. In this phase, three people were excluded, as two had current major depression and one was misusing drugs. Two people quit for health reasons (they had shortness of breath and found it hard to come to the Mood Disorders Centre/ Exeter University) and three did not show up (one of them could not come as he had a cardiac problem). Finally, 33 out of the 59-eligible

people (56 %; 95 % *CI*: 43 % to 68 %) gave their consent and were randomly allocated to the three groups: MBCT-HeLM ($N = 11$), MBSR ($N = 11$) and TAU ($N = 11$). Given the total of the sent invitations comprised 3,340 letters and summaries, this meant we managed to recruit only 1.0 % (95 % *CI*: 0.7 % to 1.4 %) of these. In the orientation sessions, one participant from the MBSR group was excluded from the study, as it was agreed that her chest pain was stress-related and not a cardiovascular disorder. As this woman had recurrent major depression, she was referred to the AcCePT Clinic for standard care.

5.4.1.2 Retention (course completion) and attrition (dropouts) rates.

Seven of the 11 participants (64 %; 95 % *CI*: 36 % to 86 %) in the MBCT-HeLM group completed the course. Of those who dropped out, three could not make the scheduled group times, two found it hard to alter their work times and one had a severe chest infection. After the third session, one woman dropped out for family reasons. Regarding the MBSR group ($n = 10$), six people (60 %) started and after the second session of MBSR, a woman dropped out as she said that it was hard for her to complete the home practice and come to the Mood Disorder Centre/University due to her serious physical disability caused by a stroke. The other people ($n = 4$) could not attend the group dates; one participant got a new job, one participant had to babysit a child, one had a surgery and one did not attend due to work-related issues.

5.4.1.3 Participant adherence.

5.4.1.3.1 Attendance. In the MBCT-HeLM group, seven out of the eight people who took part attended between six and eight sessions, while one woman only attended two. In the MBSR group, of the six who took part, four attended eight while one attended seven sessions and one woman attended two. Regarding the full-day mindfulness practice, six people from the MBCT-HeLM and five from the MBSR groups attended.

5.4.1.3.2 Home practice. We asked the MBCT-HeLM group to practise some formal and informal exercises at home for six days per week so as to integrate mindfulness into their daily life. Five out of the seven people who completed the course provided five out of the seven home practice sheets and two completed three. The average amount of practice was 5 days per week.

5.4.1.3.3 Assessment completion. Twenty-nine out of the 33 participants randomised into the trial (88 %; 95 % *CI*: 77 % to 98 %) completed the assessment at post-intervention and at the 3-month follow-up phase. All participants in the MBCT-HeLM ($n = 11$) and MBSR ($n = 10$) groups completed the post-intervention and follow-up assessments, whilst three from the TAU group ($n = 11$) did not.

5.4.1.4 Therapist adherence and competence.

For therapist adherence and competence, we used the Mindfulness-based Interventions: Teaching Assessment Criteria (MBI: TAC), which is rated on a scale from 1 (incompetent) to 6 (advanced), with the average rating being 5 (proficient) for both the MBCT-HeLM and MBSR.

5.4.1.5 Describing the primary and other outcomes data.

Table 5.3 shows the clinical characteristics at baseline for all the study outcomes (primary, secondary and process).

5.4.1.5.1 Primary outcome. Table 5.4 shows the PHQ-9 means, SDs, mean differences and 95 % confidence intervals for MBCT-HeLM vs. MBSR and MBCT-HeLM vs. TAU at post-intervention and at three-month follow-up. The mean PHQ-9 scores for the MBCT-HeLM group was 0.2 (*CI*: -3.4 to 2.9) lower at post-intervention and 1.4 (*CI*: -3.8 to 1.0) lower at three-months follow-up, than for the MBSR group. The MBCT-HeLM mean was 2.3 (*CI*: -7.23 to 2.57) lower at post-intervention and 5.2 (*CI*: -8.56 to -1.83) lower at the three-month follow-up compared to the TAU group.

5.4.1.5.2 Secondary and process outcomes. Tables 5.5 and 5.6 summarise the means, SDs, mean differences and 95 % confidence intervals across the three groups at post-intervention and three-month follow-up for the study's secondary and process outcomes. The mean blood pressure for the MBCT-HeLM was lower at three-months follow up compared to the MBSR and TAU groups. The mean GAD and CAQ scores for the MBCT-HeLM and MBSR groups were lower at post-intervention and at three-months follow-up compared to the TAU group. The mean RAND 36-Item (psychological domain) scores for the MBCT-HeLM and MBSR groups were higher at both post-intervention and at three-months follow-up than for the TAU group, while the mean RAND 36-Item (physical domain) for the MBSR group was higher at three-months follow-up compared to both the MBCT-HeLM and TAU groups. The means of the SAQ-angina stability and SAQ-diseases perception subscales for the MBCT-HeLM were higher than for the MBSR and TAU groups at both post-intervention and at three-month follow-up, while those for SAQ-physical limitations and SAQ-angina frequency for the TAU group were higher than the other two groups at three-months follow-up. The means of some of the IPQ-R subscales (timeline acute, emotional representations and consequences) for the MBCT-HeLM group were lower at both post-intervention and at three-months follow-up than for the MBSR and TAU groups, while those for the personal and treatment control subscales of IPQ-R for MBSR were lower than the means of the MBCT-HeLM and TAU groups. Regarding the process measures, the mean FFMQ for MBCT-HeLM was 4.0 higher than for the MBSR and 18.0 higher than for the TAU group, at post-intervention assessment, whilst it was 6.0 lower than for the MBSR group and 10.0 higher than for TAU, at the follow up assessment. Regarding SCS, both the MBCT-HeLM and MBSR means were higher than for the TAU group at both time-

point assessments. Finally, the mean of PANAS-Positive was higher for the MBSR group compared to the other groups at both time-point assessments.

5.4.2 The Acceptability of MBCT-HeLM

The second aim of this study was to see how acceptable MBCT-HeLM was for people with depression and cardiovascular disorders. Those who completed the MBCT-HeLM course (six people with heart conditions and one participant with stroke) described it and their overall experience as enjoyable; considering it different to other psychological programmes that they had in the past; finding it flexible and helpful. They had joined the course with the expectation that it would help in controlling physical symptoms, such as high blood pressure and heart complaints as well as understanding depression and making them calmer. Participants felt that the course had met some of their expectations in terms of understanding depression and seeing things in a different way, but less in terms of managing physical symptoms. They reported that the one-to-one orientation session was helpful in terms of understanding the content of course. They generally agreed that eight sessions represented a good course length, in that they thought that they needed time to understand mindfulness and to integrate it into their daily life and two of them felt that the course needs to be more than eight sessions. All seven participants said that the 3-Step Breathing Space exercise was the most useful and four of them found the Body Scan helpful. Participants described some challenges with the MBCT-HeLM course, in particular, being in a group and making the course a priority in their lives. Additional feedback is summarised in Table 5.7.

5.5 Discussion

The first aim of the HeLM study was to establish the feasibility of conducting an adequately powered randomised controlled trial of MBCT-HeLM for people with depression and cardiovascular disorders. The second aim was to assess how acceptable

this course was to the participants. The results were encouraging in terms of MBCT-HeLM's acceptability and participants' engagement with the course. However, the large funnel between potentially eligible participants and those who participated in the trial suggests serious challenges with regard to recruitment to such a trial.

Recruiting through GP practices was the most useful resource of the three methods used, accounting for 239 people (99 %) of all interested people. However, the percentage of those who replied to the invitation letters was only 1 %, which means that the future definitive trial will need to invite 1,000 people to get 10 consenting participants. This is less than reported for other MBCT trials (e.g., Kuyken et al., 2016). While recruiting to clinical trials is a challenge for many areas of research, this may be especially so for mental health ones (Barton, 2000; TenHave, Coyne, Salzer, & Katz, 2003), despite the high prevalence rates of mental health problems. In addition, there is limited access to evidence-based treatment. Recruitment through specialist CVD services was not successful (Figure 5.1). Cardiac nurses are typically very busy and triaging to this study added to their busy schedules. Moreover, people who visit cardiac wards often attend with unstable conditions and are not in a position to consider taking part in a psychosocial intervention like MBSR or MBCT. Moreover, direct advertising did not yield any responses.

The screening procedures worked well (Figure 5.1). In addition, conducting a second screen enabled a further check on eligibility before moving to baseline assessment. However, in the first screen, the way to ascertain whether people were suffering from depression was mostly based on asking them a few questions about their history of depression. In future studies, it would be beneficial to use an in-depth screen in the early stage of recruitment, which could capture the history of depression in detail and might increase the eligibility rate. During the orientation sessions, one female participant

was excluded due to uncertainty as to whether she was suffering cardiac problems or stress-related chest pain. In this study, the evaluative process to determine the presence of a cardiovascular disorder was based on the self-reporting of the participants. In future studies, an alternative method of determining a person's condition should be used, such as obtaining a clinical diagnosis from a potential participant's healthcare professional.

The initial drop-out rates were relatively high as 9 of the 21 (42 %) randomised people in the MBCT and MBSR groups could not attend the group dates. The drop-out rate reported in this study is similar to that in the MBCT study conducted by O'Doherty and colleagues (2015) in people with coronary heart diseases as they had 47 % drop-out rate. Specifically, only 32 out of 60 people in the MBCT group and 30 out of 57 people in the control group completed the study. In a non-controlled study (Olivo, Dodson-Lavelle, Wren, Fang, & Oz, 2009) using a shortened MBSR course with people with coronary heart diseases ($n = 35$) the drop-out rate reported was only 11% ($n = 4$), which is lower than ours. However, those two studies (O'Doherty et al., 2015; Olivo et al., 2009), targeting mindfulness and heart conditions used nonrandomised/controlled designs. In addition, the study by (O'Doherty et al., 2015) recruited people and conducted the interventions over approximately three years, while that by (Olivo et al., 2009) used a short intervention (4 MBSR sessions). In our study, the reasons given for withdrawing and dropping out varied, but health issues was the most common one provided. Research concerning elderly populations indicates that older people report higher chronic physical symptoms (Naylor et al., 2012) and therefore, it might be useful to consider delivering MBCT in ways and locations that are more convenient for this population. The second most common reason was work commitments, suggesting that it is important to consider the timing of MBCT sessions, which could lead to an increase in

the participation rate in future studies. In sum, the need to enhance the accessibility of any psychosocial intervention for this group is evidenced.

With regards to course completion, attendance and home practice, this study attained good rates of compliance. Of those people who did engage with MBCT-HeLM, they attended most sessions and engaged with the mindfulness practice throughout the course. This suggests that of the sub-group who do attend, the course is acceptable. The 3-Step Breathing Space and Body Scan seemed to be the most important practices.

Regarding assessment completion, the study had a good rate as the majority of participants completed the questionnaires at the post-intervention and follow-up phases, which indicates that the measures employed were acceptable to them. This completion rate is relatively similar to those reported in other mindfulness studies with heart conditions (O'Doherty et al., 2015; Olivo et al., 2009). The randomisation and stratification process was successful, which can be concluded because the main characteristics baselines were similar in the three groups. There was significant sample heterogeneity in terms of whether the sample was currently depressed (minor depression) or had a history of depression as well as regarding the time since the cardiac event (heart attack or stroke) and the onset of cardiovascular disorders. Importantly, there was significant heterogeneity regarding whether depression had happened before or after a CVD.

Participants who engaged with MBCT-HeLM reported a good satisfaction level with the course in terms of its content, exercises, home practice and completion of the measures. The majority of them found the 3-Step Breathing Space and Body Scan helpful. Being in a group was a challenge for some, although others said that it was helpful in terms of seeing how they were lucky compared to others. The participants' challenges in this course were mainly about how to make it a priority. Regarding the

quantitative results, it is important to emphasise that we did not set out to establish effectiveness, nor was it sufficiently powered to do so. Moreover, the wide confidence intervals illustrate the imprecision with which the intervention effects are estimated.

5.6 Summary and recommendations for the definitive trial

To summarise, to our knowledge, this is the first randomised controlled trial with three arms aimed at understanding the issues surrounding the feasibility and acceptability of delivering MBCT for people with depression and cardiovascular disorders. This study provides some methodological considerations for future studies, such as the use of the 3-arm design, randomisation and blindness, as well as rates of recruitment, retention, attrition and participants adherence. We have demonstrated that an MBCT-HeLM course was feasible and acceptable to people who took part in the study. The number of people who were randomised ($n = 33$), despite the short period of recruitment (4 out of the 7 months that we planned in early stage of the study), was good. Moreover, retention and engagement rates were encouraging. However, the pool of potentially eligible participants was much larger and suggests some key barriers to the accessibility of an intervention such as MBCT, as well as to a trial such as this. Regarding the participants' feedback on the study in relation to the course content, home practice and assessments, this was broadly positive.

In any definitive trial, further effort should be given to recruiting a more representative sample in terms of targeting people with depression and cardiovascular disorders. It would also be useful to maximise the accessibility of the intervention through, for example, offering the course in appropriate places for interested people as well as offering evening classes that would suit those in full time employment. Also, it is worth considering introducing MBCT/MBSR to participants who are inpatients on cardiology wards. In addition, using a detailed screen for depression in the early stages

of the recruitment process might lead to an increased eligibility rate. When people are provided with group dates prior to randomisation to check to see whether they are available, which improves engagement and retention. With regards to the length of follow up, in any future definitive randomised controlled trial, a longer follow-up period would be required. Finally, if the decision is made to move to a definitive trial, the study recruitment procedures will need to be revised in order to recruit a large enough sample.

5.7 Compliance with Ethical Standards

The HeLM study was approved by the Cornwall and Plymouth Research Ethics Committee (REC reference: 14/SW/0048) on 17 of April 2014. The NHS/HSC R&D management approval was obtained on 6 June 2014 (see Appendix M). The authors assert that all procedures performed in this study were in accordance with the ethical standards of the relevant national and institutional committees on human research and with the Helsinki Declaration of 1964 and its later amendments. All participants provided full informed consent.

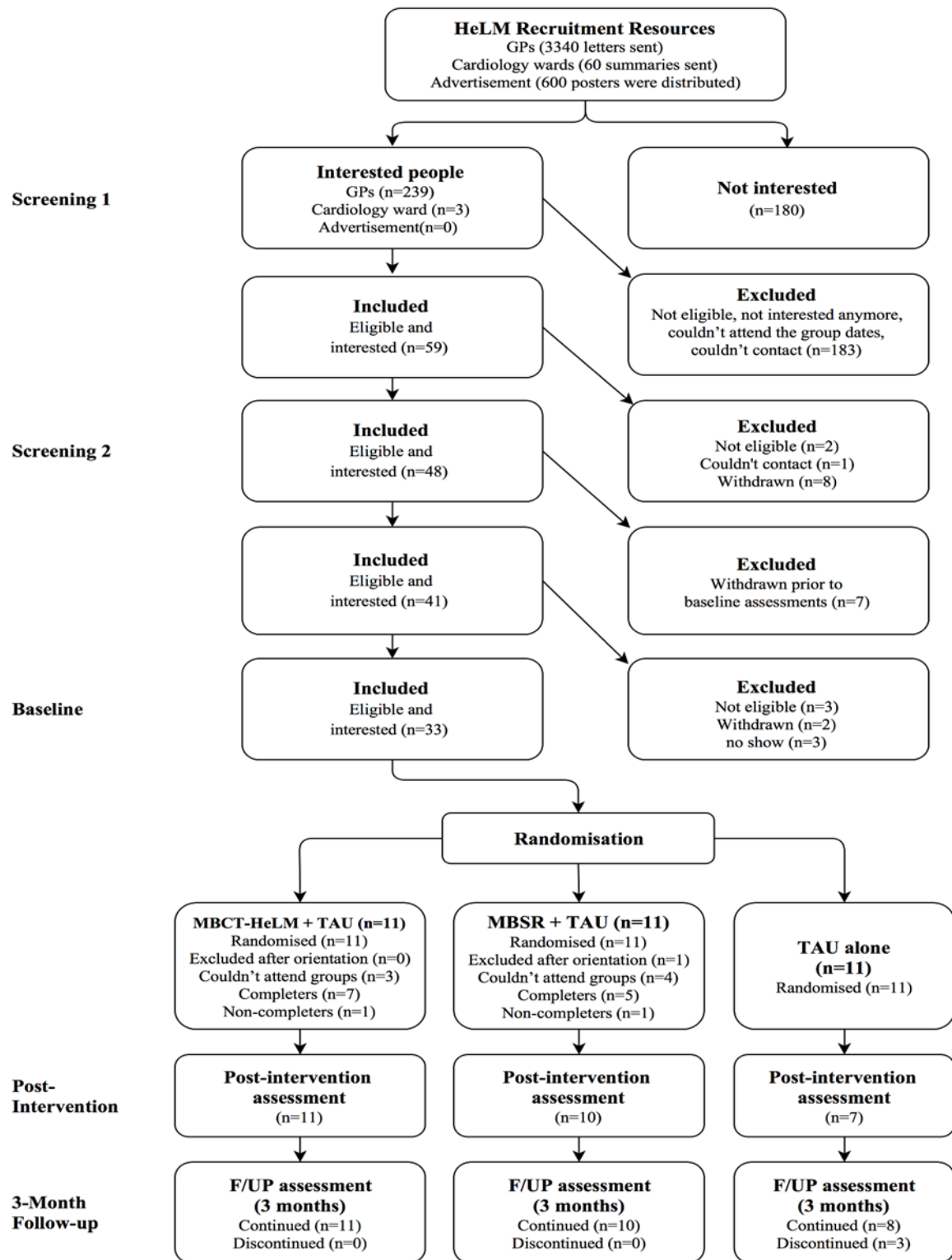


Figure 5.1. CONSORT diagram of HeLM participant flow

Table 5.1
Demographic characteristics

	Total (N = 33)	MBCT-HeLM group (N = 11)	MBSR group (N = 11)	TAU group (N = 11)
Age, mean (SD)	64.8 (10.0)	64.2 (11.6)	64.8 (10.6)	65.4 (8.4)
Gender, <i>n</i> (%)				
Male	19 (58 %)	5	5	9
Female	14 (42 %)	6	6	2
Marital status, <i>n</i> (%)				
Single	4 (12 %)	1	2	1
Married	20 (61 %)	6	6	8
Divorced	8 (24 %)	3	3	2
Widowed	1 (3 %)	1	0	0
Ethnicity, <i>n</i> (%)				
White British/Irish	31 (94 %)	10	10	11
White other	1 (3 %)	1	0	0
Asian British	1 (3 %)	0	1	0
Employment Status, <i>n</i> (%)				
Employed	10 (30 %)	4	4	2
Unemployed	2 (6 %)	1	0	1
Retired	21 (64 %)	6	7	8
Type of CVD, <i>n</i> (%)				
Heart conditions	18 (55 %)	6	5	7
Stroke	10 (30 %)	4	4	2
Hypertension	4 (12 %)	1	1	2
Not-specified	1 (3 %)	0	1	0
Having more than one CVD, <i>n</i> (%)	5 (15 %)	0	3	2
On antidepressant medication, <i>n</i> (%)				
Yes	8 (24 %)	1	2	5
No	25 (76 %)	10	9	6

Note. TAU: Treatment As Usual; SD: Standard Deviation; CVD: Cardiovascular Disorders.

Table 5.2

The main differences between MBSR, standard MBCT and adapted-MBCT (HeLM)

Session	MBSR	Standard MBCT	MBCT-HeLM: adapted for people with depression and cardiovascular disorders.
Orientation session	Learning about stress and mindfulness.	Learning about the factors associated with the onset and maintenance of depression.	Learning about the factors associated with the onset and maintenance of long term physical and mental health problems.
Session 1	Seeing the significance of autopilot in our lives.	Seeing the significance of autopilot in our lives.	Seeing the significance of autopilot in our lives. Emphasising turning towards bodily experience.
Session 2	Perception and creative responding. How we see things.	The relationship between thoughts and feelings and the way this affects mood.	The relationship between thoughts and feelings and the way this affects mood.
Session 3	Pleasure and power of presence.	The body is a place to be with experience. Discovering 'being present'.	The body is a place to be with experience. Discovering 'being present'.
Session 4	Shadow of stress: learning about our patterns of reactivity.	Getting to know territory of depression.	Getting to know territory of low mood, stress and anxiety. Learning experientially how maintenance cycles play out. Introduce the RAIN acronym: Recognising, allowing, inquiry and thoughts are Not facts.
Session 5	Finding space for responding.	Bringing a sense of allowing things to be. Acceptance.	Title of session changed to (Softness and Strength). -The RAIN acronym progresses here to the Allow.
Session 6	Working with difficult situations. Communication.	Thoughts are not facts. Negative moods affect our experience. Recognising patterns of thoughts can help us.	Title of session changed to Symptoms as messages from the body; thoughts are not facts. The RAIN acronym progresses here to the Inquiry and thoughts are Not facts.
All day practice	This all-day session is a main part of MBSR.	This all-day session is an optional part of MBCT.	This all-day session is part of MBCT-HeLM to provide enough time for practice.
Session 7	Cultivating kindness.	Recognizing the warning signs of depression Self-care: nourishing activity	More focus on stress as well as low mood. Self-care: nourishing activity
Session 8	Keeping mindfulness alive.	Keeping mindfulness alive.	Keeping mindfulness alive.

Table 5.3

Clinical characteristics at baseline

	MBCT-HeLM group		MBSR group		TAU group	
	Mean	SD	Mean	SD	Mean	SD
Primary outcome						
Patient Health Questionnaire-9 (PHQ-9)	8.4	4.8	8.5	4.6	7.0	5.0
Secondary outcomes						
Blood Pressure						
Blood pressure / Systolic	126.7	10.5	142.3	21.8	128.5	21.3
Blood pressure / Diastolic	73.8	12.7	77.6	14.3	70.6	8.3
Generalised Anxiety Questionnaire-7 (GAD-7)	8.2	3.5	7.0	5.2	4.8	3.3
Cardiac Anxiety Questionnaire (CAQ)	17.0	9.1	22.2	8.6	34.0	13.6
RAND 36-Item Physical	53.3	18.2	43.0	24.3	59.1	31.5
RAND 36-Item Psychological	53.1	21.2	42.3	13.3	51.8	19.3
Five-Facet Mindfulness Questionnaire (FFMQ)	121.0	15.4	122.0	17.9	113.7	16.4
Self-Compassion Scale (SCS)	2.5	0.5	2.6	0.6	2.4	0.6
PANAS-Positive affect	30.3	7.5	27.4	5.9	25.3	9.4
PANAS-Negative affect	20.0	8.5	17.4	6.1	18.0	6.9
Illness Perception Questionnaire-Revised (IPQ-R)						
IPQ-R timeline acute/chronic	20.9	7.1	23.6	4.5	25.7	4.4
IPQ-R timeline cyclical	11.7	5.1	10.6	3.4	11.0	5.2
IPQ-R consequences	17.1	5.1	20.3	6.9	20.2	3.9
IPQ-R personal control	22.1	4.9	22.2	4.6	19.9	5.4
IPQ-R treatment control	18.9	3.5	15.9	2.8	17.3	4.4
IPQ-R illness coherence	17.5	4.7	19.2	5.8	19.6	4.7
IPQ-R emotional representations	18.3	6.2	20.7	2.6	19.7	4.3
The Seattle Angina Questionnaire (SAQ)						
SAQ- physical limitations	52.5	13.8	48.1	17.8	37.8	18.7
SAQ- angina stability	56.0	21.9	36.6	8.1	36.0	16.7
SAQ- angina frequency	70.5	11.5	70.6	14.8	58.0	27.0
SAQ- treatment satisfaction	59.8	17.0	62.3	10.1	68.0	13.8
SAQ- disease perception	52.1	20.6	47.8	19.2	43.8	28.6

Note. TAU: Treatment As Usual; SD: Standard Deviation.

Table 5.4

Comparison of PHQ-9 at post-intervention and follow-up

Outcome	MBCT-HeLM (N = 11)	MBSR (N = 10)	TAU (N = 8)	MBCT-HeLM vs. MBSR		MBCT-HeLM vs. TAU	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean diff.	95% CI	Mean diff.	95% CI
Baseline	8.4 (4.8)	8.5 (4.6)	7.0 (5.0)				
Post-intervention	6.1(3.1)	6.3 (3.6)	8.4 (6.3)	-0.2	-3.4 to 2.9	-2.32	-7.23 to 2.57
3- months follow-up	3.8(2.5)	5.2 (2.4)	9.0 (4.1)	-1.4	-3.8 to 1.0	-5.20	-8.56 to -1.83

Note. PHQ-9: Patients Health Questionnaires-9; TAU: Treatment As Usual; SD: Standard Deviation; CI: Confidence Interval.

Table 5.5
Comparison of secondary outcomes at post-intervention

Outcomes	MBCT-HeLM (N = 11)	MBSR (N = 10)	TAU (N = 7)	MBCT-HeLM vs. MBSR		MBCT-HeLM vs. TAU	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean diff.	95 % CI	Mean diff.	95 % CI
Blood pressure							
Systolic blood pressure (mmHg)	130.4 (20.7)	143.8 (20.7)	129.8 (14.8)	-13.4	-42.5 to 15.7	0.6	-20.3 to 21.4
Diastolic blood pressure (mmHg)	73.2 (16.4)	76.5 (17.8)	73.5 (9.3)	-3.3	-24.2 to 17.7	-0.3	-15.9 to 15.3
GAD-7	4.8 (4.8)	4.4 (2.8)	6.4 (3.9)	0.4	-3.6 to 4.4	-1.6	-6.2 to 3.0
CAQ*	18.3 (14.3)	18.0 (1.4)	30.5 (13.6)	0.3	-16.5 to 17.2	-12.1	-33.1 to 8.8
RAND 36-Item Health Survey 1.0							
RAND 36-Item Physical	49.5 (15.3)	56.4 (28.1)	59.1 (32.7)	-6.9	-27.6 to 13.9	-9.6	-40.2 to 21.2
RAND 36-Item Psychological	55.5 (19.1)	60.8 (14.6)	48.7 (23.7)	-5.3	-21.6 to 11.0	6.8	-14.7 to 28.3
FFMQ (Total)	128.0 (18.0)	124.0 (18.3)	110.0 (6.7)	4.0	-15.6 to 23.4	18.0	2.1 to 33.3
SCS (Total)	2.6 (0.6)	2.8 (0.8)	2.4 (0.7)	-0.2	-0.9 to 0.5	0.2	-0.5 to 0.8
PANAS-Positive	25.3 (7.1)	32.7 (4.3)	28.2 (7.4)	-7.4	-13.6 to -1.3	-2.9	-10.6 to 4.7
PANAS-Negative	18.7 (9.8)	16.3 (6.6)	19.4 (9.1)	2.3	-6.3 to 11.0	-0.7	-10.8 to 9.3
IPQ-R							
IPQ-R timeline acute/chronic	18.1 (3.6)	18.6 (2.8)	18.7 (6.7)	-0.5	-3.8 to 2.8	-0.6	-6.0 to 4.7
IPQ-R timeline cyclical	11.5 (4.0)	11.1 (3.2)	10.4 (4.4)	0.4	-3.4 to 4.3	1.1	-3.5 to 5.7
IPQ-R consequences	19.7 (6.2)	18.8 (5.3)	19.0 (6.1)	0.9	-5.0 to 6.6	0.7	-5.8 to 7.2
IPQ-R personal control	23.2 (3.7)	19.2 (3.9)	23.1 (4.8)	4.0	0.1 to 7.8	0.1	-4.4 to 4.5
IPQ-R treatment control	16.8 (2.2)	13.8 (4.2)	17.7 (2.4)	3.0	-0.4 to 6.5	-0.9	-3.4 to 1.7
IPQ-R illness coherence	20.3 (2.3)	16.5 (5.9)	18.8 (2.8)	3.8	-0.7 to 8.4	1.5	-1.3 to 4.3
IPQ-R emotional representations	17.5 (5.2)	19.3 (5.1)	18.1 (4.6)	-1.8	-7.2 to 3.6	-0.6	-6.0 to 4.8
SAQ**							
SAQ- physical limitations	43.8(19.2)	41.8(21.4)	41.9(5.3)	2.0	-25.7 to 29.7	1.9	-25.8 to 29.5
SAQ- angina stability	52.0(17.8)	60.0(20.0)	50.0(20.5)	-8.0	-35.7 to 19.8	2.0	-1.3 to 65.3
SAQ- angina frequency	68.1(13.3)	68.3(13.6)	45.8 (17.6)	-0.2	-18.8 to 18.2	22.3	-6.1 to 50.5
SAQ- treatment satisfaction	58.0 (18.5)	64.7(11.4)	65.0 (11.9)	-6.7	-29.2 to 15.8	-7.0	-36.8 to 22.8
SAQ- disease perception	50.6 (23.4)	58.6(12.8)	44.4 (27.7)	-8.0	-35.5 to 19.5	6.2	-38.3 to 50.8

Note: TAU: Treatment As Usual; SD: Standard Deviation; CI: Confidence Intervals; GAD-7: Generalised Anxiety Questionnaire-7; CAQ: Cardiac Anxiety Questionnaire; FFMQ: Five Facet Mindfulness Questionnaire; SCS: Self-Compassion Scale; PANAS: Positive and Negative Affect Scale; IPQ-R: Illness Perception Questionnaire-Revised. SAQ: Seattle Angina Questionnaire; * CAQ was completed by participants with heart conditions only (MBCT, n=6; MBSR, n=5; TAU, n=3); ** SAQ was completed by participants with heart conditions only (MBCT, n=6; MBSR, n=5; TAU, n=3).

Table 5.6
Comparison of secondary outcomes at 3-month follow-up

Outcomes	MBCT-HeLM (N= 11)	MBSR (N= 10)	TAU (N= 8)	MBCT-HeLM vs. MBSR		MBCT-HeLM vs. TAU	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean diff.	95% CI	Mean diff.	95% CI
Blood pressure							
Systolic blood pressure (mmHg)	122.6 (16.3)	130.4 (14.1)	127.8 (14.8)	-7.8	-26.4 to 10.8	-5.2	-24.3 to 13.9
Diastolic blood pressure (mmHg)	65 (20.5)	73 (15.2)	70.7(9.6)	-8.0	-29.9 to 13.9	-5.7	-24.8 to 13.4
GAD-7	3.2 (2.4)	3.5 (1.6)	8.0 (5.0)	-0.3	-2.4 to 1.8	-4.8	-8.6 to -0.9
CAQ*	16.6 (10)	23.0 (4.9)	30.0 (6.2)	-6.3	-17.5 to 4.8	-13.3	-26.4 to -0.2
RAND 36-Item Health Survey 1.0							
RAND 36-Item Physical	51.6 (21.4)	59.1 (24.4)	54.9 (32.4)	-7.5	-29.0 to 14.0	-3.3	-32.1 to 25.7
RAND 36-Item Psychological	63.8 (18.2)	61.3 (18.3)	51.6 (20.9)	2.5	-14.8 to 19.8	12.1	-6.9 to 31.2
FFMQ (Total)	125 (19.0)	131 (26.4)	115 (14.6)	-6.0	-28.0 to 14.8	10.0	-7.3 to 26.7
SCS (Total)	2.8 (.51)	2.9 (0.69)	2.7 (0.6)	-0.1	-0.8 to 0.4	0.1	-0.1 to 1.0
PANAS-Positive	27.9 (6.1)	32.1 (9.8)	28.3 (9.9)	-4.2	-11.8 to 3.4	-0.4	-8.2 to 7.3
PANAS-Negative	18.6 (7.4)	18.8 (7.7)	17.3 (9.6)	-0.2	-7.9 to 6.4	0.8	-7.4 to 9.0
IPQ-R							
IPQ-R timeline acute/chronic	21.3 (5.5)	23.8 (4.1)	26.7 (3.5)	-2.6	-7.5 to 2.3	-5.5	-10.2 to -0.7
IPQ-R timeline cyclical	11.5 (3.7)	10.0 (3.7)	11.4 (4.7)	1.5	-2.1 to 5.2	0.2	-3.9 to 4.2
IPQ-R consequences	18.3 (4.9)	20.4 (5.8)	20.6 (5.6)	-2.1	-7.3 to 3.1	-2.4	-7.4 to 2.7
IPQ-R personal control	22.1 (3.5)	23.5 (3.6)	21.6 (4.4)	-1.4	-4.9 to 2.1	0.5	-3.4 to 4.3
IPQ-R treatment control	17.0 (2.6)	17.3 (2.9)	19.0 (2.7)	-0.3	-3.0 to 2.5	-2.0	-4.6 to 0.6
IPQ-R illness coherence	19.3 (4.0)	18.1 (5.1)	20.0 (4.3)	1.1	-3.2 to 5.5	-0.7	-4.7 to 3.2
IPQ-R emotional representations	17.9 (4.8)	18.6 (6.1)	17.8 (6.1)	-0.7	-6.0 to 4.6	0.1	-5.1 to 5.4
SAQ**							
SAQ- physical limitations	46.6 (14.2)	43.5 (19.5)	48.1 (19.5)	3.1	-18.9 to 25.1	-1.5	-28.1 to 25.1
SAQ- angina stability	63.3 (15.0)	50.0 (24.5)	40.0 (17.0)	13.3	-12.8 to 39.5	23.3	-4.1 to 50.8
SAQ- angina frequency	72.2 (10.0)	66.6 (11.7)	75.0 (11.7)	5.6	-8.6 to 19.7	-2.8	-23.5 to 17.9
SAQ- treatment satisfaction	63.4 (8.8)	62.6 (11.0)	64.2 (16.8)	0.8	-12.1 to 13.7	-0.8	-22.0 to 20.4
SAQ- disease perception	56.6 (13.1)	51.1 (19.6)	46.0 (28.2)	5.6	-15.9 to 27.1	10.0	-23.3 to 43.3

Note: TAU: Treatment As Usual; SD: Standard Deviation; CI: Confidence Intervals; GAD-7: Generalised Anxiety Questionnaire-7; CAQ: Cardiac Anxiety Questionnaire; FFMQ: Five Facet Mindfulness Questionnaire; SCS: Self-Compassion Scale; PANAS: Positive and Negative Affect Scale; IPQ-R: Illness Perception Questionnaire-Revised. SAQ: Seattle Angina Questionnaire; * CAQ was completed by participants with heart conditions only (MBCT, n=6; MBSR, n=5; TAU, n=3); ** SAQ was completed by participants with heart conditions only (MBCT, n=6; MBSR, n=5; TAU, n=4).

Table 5.7

Themes and sample quotes from the HeLM acceptability interviews

Themes	Summary	Quotes
Diversity of expectations	Participants joined the course with different expectations of it. Two hoped to get benefit for their heart condition and high blood pressure as well as their depression. Another two wanted something to help with their depression and anxiety, so they could see things in a different and calmer way. One woman joined the course as she had a personal interest in learning cognitive therapy and meditation. One other participant joined the course without any expectations and he reported that he had no enough information about the course.	<p>“Well basically that I'd come out feeling calmer and look at things in a different perspective. Instead of being a black and white person seeing things in a calmer way perhaps” (Participant 3)</p> <p>“I wanted to know about depression. Because you never know enough about it and maybe that's probably why we're depressed because we don't know enough how we need to avoid some things (Participant 7)</p>
Motivation	The reasons that made people to take part in the course were different, such as meeting other people, the experience its self (e. g trying new things, coming to the university or learning meditation). One participant said that it was an opportunity and he thought he should take advantage of it. Other participants pointed out that the nature of MBCT, as a kind of psychotherapy, would not cause them any harm. Another mentioned attending so it would be possible to avoid psychiatric medications. Two participants wanted to deal with their physical conditions (heart conditions and blood pressure) and depression. Another two participants wanted to get help with their depression.	<p>“I wanted something to help me, I felt I needed some help with my condition both with the mental condition I found myself in after I got ill and the illness itself and I thought anything like this is at least worth trying” (Participant 2)</p> <p>“Because at the time I was feeling rather down, and I thought it would be a way of speaking to somebody, mixing with different people and communicating to me is pretty important anyway” (Participant 3)</p> <p>“I'm a supporter of anything that will take us away from chemicals. This is not a chemical or a physical intervention, it's about the mind. and therefore, you can only benefit from it” (Participant 5)</p>
Challenges 1. Being in group	Five of the seven participants joined the group with some worries around being in a group, mainly being worried about talking to new people, talking about personal issues with others and/or due to a language barrier. However, these people's experience was very positive, with reporting that the environment was encouraging, and they worked well as a team. One of the things that seemed to help people to deal with their worries is that there was no pressure to talk or share feelings about depression or their physical symptoms, such as having a heart attack or stroke, if they did not wish to do so. Participant 1 did not see the course as a group therapy but more as an opportunity to share personal experiences with others, while Participant 5 said that being in a group helped in not being introspective.	<p>Oh, my God, I was worried. First because of my language and second it was really difficult to meet new people, you know that feeling, having looked at you, you know, maybe someone start to ask you know what you've done before but yes it was a really different experience I was talking to nice people” (Participant 7).</p> <p>“I haven't ever taken part in what I understand to be group therapy, but I think it is people sharing their experiences” (Participant 1)</p> <p>“I think that if it were not a group it would be very easy to become extremely introspective in your perceptions of what was going on and why you were doing it. When you have a group, there is this group thing that takes over”. (Participant 5)</p>

Table 5.7 cont.

Themes and sample quotes from the HeLM acceptability interviews

Themes	Summary	Quotes
2. Making mindfulness a priority	Four participants agreed that making the course a priority in their lives had been a challenge for them. They reported how they needed to push themselves and had to allocate time to undertaking homework every day.	“If I were in your position I would be very aware that people have difficulties and you have to persuade them to priorities this project, the exercises” (Participant 5).
Effective techniques	<p>1. Orientation session: The seven participants seemed to agree that the orientation session with the therapist was very helpful in terms of providing good information about the course and what was going happen. They reported that the therapist was easy to talk to.</p> <p>2. Exercises: The seven participants agreed that the 3-step breathing space was useful for different reasons. For example, participant 5 thought that it is short and that it suited his lifestyle as he could use it anywhere, while participant 2 said that he felt better regarding his breathing with this exercise. The body scan was useful for four participants. For example, participant 1 described her experience with it as it having helped her to see how lucky she was comparing to other people who had physical problems. Also, talking to other people and the therapist seemed to be helpful to some participants.</p> <p>3. Homework and Questionnaires Participants 1, 3, 6 and 7 described their experience with doing homework as being easy, but they had to allocate time to undertaking it. Participant 4 thought that it was demanding. Participants 2 and 5 thought that the homework was flexible and it had helped them to do what they wanted to do. Regarding the questionnaires, participants agreed that completing them was fine. However, some said that some items did not apply to them and some were repetitive.</p> <p>4. The course overall It seemed that the course as overall was acceptable to people. For example, three participants liked how flexible it was. Participant 1 described the course as delivering “A more relaxed attitude to life”.</p>	<p>“The breathing space suits my life and the way I live” (Participant 5).</p> <p>“When I'm faced with a stressful situation the first thing that happens is my breathing shuts down a little bit, there is already a heart condition that causes a problem with that so it's twice as bad but then I think about the responsive breathing, the breathing practice and It does seem to help there's no doubt about that” (Participant 2).</p> <p>“it was quite demanding and filling in the forms but then if you didn't have the forms I think there wouldn't have been the incentive to keep going so yes it was quite demanding but I think it probably needed to be quite demanding” (Participant 4).</p> <p>“A more relaxed attitude to life. I remember we were asked that question in the group and the answer just came to me. I hadn't articulated it before. I felt that the words had been put into my mouth almost without my having to think about them” (Participant 1).</p>

Table 5.7 cont.

Themes and sample quotes from the HeLM acceptability interviews

Themes	Summary	Quotes
Ineffective techniques	<p>1. Exercises: Six out of the seven participants found that the movement exercise was not helpful. Four said that as they had other physical complaints that limited their ability to do it. Participant 3 said that it was very slow, so she did not like it. While participant 7 thought that it did not help her to feel calm. However, participant 5, who had hypertension, found this exercise helpful.</p> <p>2. Handouts. Participant 2 pointed to that there was a need to emphasise more the fact that this course was for people with CVD. He also mentioned that some of terms in the handout needs to be explained further, such as automatic pilot.</p>	<p>“Do you know I've gone to the whole 8 weeks and this business about it being special for heart conditions, hasn't really been emphasized very much. I know that's what you've got because you've got two groups, a control group and all the rest of it but there wasn't a lot of mention of that of the physical side of people's conditions in the course. It was about the mindfulness itself” (Participant 2).</p>
Physical /Psychological benefits	<p>The benefits that participants obtained from the course were mainly around breathing, understanding depression and facing stress. For example, two participants reported that the course had helped them regarding their breathing and three said that it was helpful in terms of having another way of controlling stress as well as providing them with a different way of seeing things. One participant thought that after having the course she was able to understand depression better.</p>	<p>“I think it's helped some of the way I think about things, not necessarily to do with my illness but maybe to do with if I feel depressed I can think 'these are just thoughts' I try to if I'm thinking very negative thoughts I could sometimes look at the thoughts and think I don't need to think like this, so it had helped me” (Participant 4).</p> <p>“First I feel very clear about that now, about depression and that so I can explain to someone myself what is this and how you can fight that” (Participant 7).</p>

Chapter 6.0

General Discussion

6.1 Summary of the PhD Rationale

Comorbid depression is highly prevalent in cardiovascular disorders (CVDs), leading to worse medical outcomes, high morbidity, poor quality of life and high health care costs (Baumeister, Haschke, Munzinger, Hutter & Tully, 2015; Dickens, Cherrington, & McGowan, 2012; Naylor et al., 2012; Pelletier et al., 2015; Rustad, Stern, Hebert & Musselman, 2013; Win et al., 2011). A wide range of psychological, social and biological factors have been suggested to explain this comorbidity. Notably, psychological factors, such as rumination, health related worry, self-efficacy and self-care have been found to be associated with both conditions (Greco et al., 2014; Holzapfel et al., 2009; Loo et al., 2016; Riegel, Lee & Dickson, 2011; Tovar et al., 2015). As a result, it has been suggested that any psychological intervention targeted at treating co-morbid depression in CVDs needs to take account of these factors (Greco et al., 2014).

Mindfulness-Based Cognitive Therapy (MBCT), which was originally designed for relapse prevention and residual symptoms treating, has been found to be effective regarding the psychological symptoms of people suffering from physical health conditions (Schoultz, Atherton, & Watson, 2015; Van Der Lee & Garssen, 2012; van Son et al., 2014). MBCT has also shown promising results with some of the common psychological links between depression and CVDs, such as rumination and worry (Kingston, Dooley, Bates, Lawlor, & Malone, 2007; Michalak, Holz, & Teismann, 2011; van Aalderen et al., 2012). However, whether MBCT can help manage comorbid depression in this population remains unclear and hence, this PhD, as part of Heart and Living Mindfully (HeLM) project, was aimed at addressing this issue.

In this Chapter, a summary of the PhD thesis (HeLM project phases) aims, findings and the discussion of the findings are provided. Also, some lessons learnt from the feasibility trial are provided. Finally, the strengths and limitations of each phase and suggestions for future research will be discussed

6.2 Summary of the PhD Aims

This PhD was aimed at developing a bespoke MBCT for people with comorbid depression and CVDs through a phased approach, including establishing the evidence base around MBCT adaptations (Chapters 2.0 and 3.0) and then piloting a bespoke MBCT (Chapter 4.0). A main part of this project was to establish the feasibility and acceptability of this bespoke MBCT using a 3-arm randomised controlled trial (Chapter 5.0). Besides the aim of adapting MBCT for people with CVDs, the core goal was to increase its effective and implementation in practice. Accordingly, the “HeLM” project was established based on the UK Medical Research Council guidelines (MRC) for developing complex interventions (Craig et al., 2008) and the National Institutes of Health (NIH) stage model (Onken, Carroll, Shoham, Cuthbert & Riddle, 2014)

6.3 HeLM phase 1 (Basic Research)

6.3.1 Systematic review.

6.3.1.1 Aims. A systematic review was conducted as part of establishing the evidence base for adapting MBCT for people with depression and CVDs. In the review, the evidence in relation to how mindfulness interventions (MBCT/MBSR) can produce beneficial health effects for people with physical and/or psychological conditions was presented, with the main focus being on investigating the common and specific mechanisms across both conditions. Moreover, the methodological adequacy of the evidence was evaluated systematically using a framework of the criteria for examining mechanisms of change in treatments.

6.3.1.2 Findings. We found four studies with physical conditions populations and 14 studies with psychological conditions populations. A wide range of potential mindfulness mediators, have been studied, including mindfulness, rumination, worry, self-compassion, cognitive and emotional reactivity. The most consistent result was that greater changes in mindfulness are associated with better psychological outcomes. Some studies suggested that rumination and worry mediated the effects of MBCT/MBSR in both physical and psychological conditions. Importantly, the review suggests that some factors show up as a candidate universal (common) mechanism or mediator of change in MBCT/MBSR across psychological and physical populations (e.g., enhancing mindfulness) whilst others seem promising as specific to particular populations (e.g., decentring from negative thinking with depression). Lastly, very few studies have fully met the framework criteria for examining treatment mechanisms.

6.3.1.3 Discussion of the findings. The systematic review examining mechanisms of action regarding MBCT/MBSR highlighted that limited attention has given to studying mechanisms in people with physical conditions when compared with psychological conditions and hence, main focus has been on psychological not physical outcomes. This was not surprising, as the field of mindfulness interventions with physical condition populations is still in its very early phase. It was clear that examining physical condition populations related mediators has generally been ignored, although a wide range of mechanisms have been studied.

A methodology evaluation revealed that the field of examining mechanisms of MBCT/MBSR in both physical and psychological populations has clear methodological limitations and hence, that no definitive conclusions can be drawn. This is in consistent with other recent reviews (Gu, Strauss, Bond & Cavanagh, 2015; van der Velden et al., 2015). The

limitations that noticed were mainly in relation to time-points used and the assessment methods.

In CVD populations, we hypothesise that MBCT-HeLM is intended to target more specifically the specific mechanisms that drive both depression and cardiovascular disorders (e.g., rumination and worry specific to CVD, illness beliefs, lower self-efficacy and poor self-care) as well as the general mechanisms targeted by any mindfulness-based intervention (Alsubaie et al., 2017). This is, in part, supported by our HeLM systematic review (Alsubaie et al., 2017). For example, rumination was considered as a mediator of the effects of MBCT and MBSR in three studies focusing on psychological conditions and in both studies investigating its role in physical conditions. Also, worry was found to mediate the relationship between MBCT/MBSR and psychological problems in all the studies for psychological and physical conditions.

It seems that some variables, such as changes in mindfulness and rumination, show up as universal mechanisms or mediators of action in MBCT/MBSR in both populations (psychological and physical). Rumination/worry as universal mechanisms would appear to have specific manifestations in a given population (e.g., repetitive thinking as a universal mechanism; in recurrent depression, the focus is on the causes, meanings and consequences of depression), however, in cardiovascular disorders, there may be a different focus (e.g., it may be on the causes, meaning and consequences around physical health). These hypotheses need to be tested in a definitive trial.

6.3.2 Secondary analysis.

6.3.2.1 Aims. Another part of establishing the evidence base was a study investigating the role of MBCT on medical symptoms. This was a secondary analysis of a large RCT that compared MBCT plus support with tapering or discontinuing maintenance antidepressant medication (MBCT-TS) along with maintenance of antidepressants (m-ADM) in terms of depression outcomes (relapse and residual symptoms) and a range of secondary outcomes, including medical comorbidities, in people with recurrent depression as assessed by MSCL (PREVENT; Kuyken et al., 2016).

6.3.2.2 Findings. To establish the structural factor of the main measure (MSCL), an exploratory factor analysis was carried out and the findings showed the MSCL measure loaded onto two factors (physical and psychological). Also, the findings showed that the MBCT and m-ADM groups did not differ significantly in their physical or psychological symptoms, as assessed by the MSCL, at follow-up assessments. The moderation analyses indicated that baseline total medical symptoms as well as the two factors (physical and psychological) moderate the effects of MBCT vs. m-ADM on the relapse rate at both follow-up assessments. Regarding the residual depressive symptoms, the findings showed that baseline total score of MSCL and physical factor of the MSCL have a moderating effect at different time assessments.

6.3.2.3 Discussion of the findings. Whilst the findings did not show any differences between MBCT vs. m-ADM regarding medical symptoms, the significant main effects meant that medical symptoms, especially the physical factors, had a negative impact on depression relapse and residual symptoms, regardless of the group. This highlights that medical symptoms played an important role on depression outcomes.

The findings of moderation analysis indicated that baseline medical symptoms played a role as a moderator of the effects MBCT vs. m-ADM on depression outcomes. Moreover,

this was clearer regarding the physical component than for the psychological one of the MSCL. This was inconsistent with a recent study (Nykliček et al., 2016) in that it showed that medical comorbidity did not affect the relationship between MBCT and psychological outcomes in people with diabetes. However, our study looked at physical symptoms while the previous work was interested in physical conditions. Interestingly, those undertaking MBCT seemed to outperform the antidepressant group in subgroups of high medical symptoms as well as high physical ones. To summarise, physical symptoms can play a role as moderators of the effects of MBCT on depression outcomes. The better results that MBCT showed in terms of dealing with high baseline medical symptoms may indicate that it has the potential of helping people with physical conditions populations.

To summarise, the basic research phase provided the HeLM team with useful information regarding developing the MBCT-HeLM manual (for information on the early basic research work see Appendix A). This PhD systematic review highlighted that mindfulness as mediator showed up as a consistent mediator that played a role in both physical and psychological conditions. Thus, it may be that people with a physical condition, such as CVD, would gain benefits from taking part in an intervention that includes a mindfulness construct. The review also found that rumination and worry were important common mediators in both physical and psychological conditions. Hence, the manual was adapted to include those two measures through expanding the MBCT focus from depression specific mechanisms to specific cardiovascular ones (Larsen & Christenfeld, 2009; Rozanski, Blumenthal & Kaplan, 1999). Regarding the secondary analysis of the impact of MBCT on physical symptoms, the study indicated that MBCT may have a potential to work better with people with high physical conditions. Consequently, the next level of the MRC guidelines that included developing the manual and testing its acceptability in a pilot group was applied.

6.4 HeLM phase 2 (Manual Development Piloting).

6.4.1 Aims.

To develop the intervention, we followed the MRC framework (Craig et al., 2008) and NIH model (Onken et al., 2014). This began with adapting and piloting (Chapter 4.0). The pilot group was aimed mainly at further development of a bespoke MBCT for people with depression and cardiovascular disorders. This group was also convened for assessing the bespoke MBCT's acceptability for this population, testing the feasibility of recruitment to the group and to see whether the course was helpful for the participants in terms of decreasing depressive symptoms as well as negative illness perceptions and increasing their mindfulness skills.

6.4.2 Findings.

The changes that were made to the original MBCT manual were based on working with service user feedback going through the manual session by session. The changes generally were around the main themes, meditation practices and home exercises, with there being particular focus on self-care, self-efficacy and the adjustments in relation to having a long-term health condition. Also, we aimed to expand the MBCT focus from depression specific mechanisms to cardiovascular specific mechanisms. Some of the exercises were shortened (For more details, see Chapter 4.0, Table 4.1). The pilot group showed high acceptability with no drop out and high engagement in terms of attendance rate and weekly measures completion. Pre-follow up comparisons and clinical significance methods results showed some improvements changes in the participants' depressive symptoms, mindfulness skills at the three-month follow-up.

6.4.3 Discussion of the findings.

The standard MBCT manual was adapted for people with comorbid depression and CVDs with the aim being to focus on the underlying links between those conditions. Teasdale

et al. (2003) have proposed that mindfulness interventions could have an impact on common mechanisms in different populations. Crane and colleagues argued that any adaptation for new populations and contexts needs to consider carefully what changes are needed to enhance acceptability and effectiveness (Crane et al., 2017).

For the HeLM manual, the same standard MBCT length of course and most of the sessions were kept. The changes that were added to some sessions were aimed at expanding the MBCT focus from depression specific mechanisms to cardiovascular specific mechanisms (Larsen & Christenfeld, 2009; Rozanski, Blumenthal & Kaplan, 1999). In addition, there was careful attention paid to body sensations in terms of avoiding participants with serious cardiac event experiences (e.g., heart attack or stroke) having to attend suddenly to bodily sensations that could increase the anxiety of a further cardiac event. Moreover, we considered some other factors, including self-efficacy and self-care that have been associated with worse cardiac and psychological outcomes (Greco et al., 2014; Loo et al., 2016; Morgan et al., 2014; Riegel et al., 2011; Sarkar et al., 2007; Schoormans et al., 2014; Stafford et al., 2009; Tovar et al., 2015; van der Wal et al., 2016; Volz et al., 2016). The manual piloting was successful with high acceptability, which meant MBCT-HeLM was well-tolerated and not harmful, so we moved to next step of the MRC framework.

6.5 HeLM phase 3 (Feasibility and Acceptability RCT)

6.5.1 Aims.

In line with the second element of the MRC framework and stage 1 (phase B) in the NIH model regarding piloting/feasibility of the targeted intervention, a randomised controlled trial on the feasibility and acceptability of MBCT for people with depression and cardiovascular disorders was conducted. The study was aimed, primarily, at drawing out the key uncertainties around the intervention and trial design that needed to be resolved to help

decide whether to proceed to a definitive trial. Also, the acceptability of this course was established.

6.5.2 Findings.

The findings indicated that recruiting people through GPs was the most helpful method of getting participants, while targeting a cardiology department and distributing advertisements were not successful. High withdrawal rates (between initial recruitment and randomisation) and dropout rates (between randomisation and prior interventions started) were noticed. Other parameters, including randomisation, blinding and inclusion/exclusion criteria were tested. In addition, the study showed positive indicators of acceptability of the course content, home practice, the measures and participants' adherence (attendance, retention) for participants who started it.

6.5.3 Discussion of the findings.

The feasibility trial has provided HeLM team with essential information regarding feasibility parameters, such as recruitment, retention and attrition rates as well as in relation to randomisation and blinding. This work was aimed at examining the feasibility of conducting a definitive trial and consequently, reducing the risk of failure of any future mindfulness RCT targeting comorbid depression and CVD populations.

The current study's recruitment rate (number of assessed people) (7.1 %) was lower than that reported (between 30 % to 74 %) in mindfulness studies targeting heart conditions populations (O'Doherty et al., 2015; Olivo et al., 2009; Nyklíček et al., 2014). This could have been due to the nonrandomised/controlled designs used in studies (O'Doherty et al., 2015; Olivo et al., 2009), the longer length of recruitment (two to three years) in studies (Nyklíček et al., 2014; O'Doherty et al., 2015) or the boarder inclusion criteria for depression (Olivo et al., 2009; Nyklíček et al., 2014).

Our study initial dropout rate (42 %) is similar to that reported (47 %) in the study (O'Doherty et al., 2015) using an 8 MBCT sessions. Those rates are higher than those reported (16 %) in other mindfulness studies using the full version of MBCT with psychological conditions populations (Khoury et al., 2013), indicating that the attrition issue is another challenge to mindfulness researchers working with CVD populations.

Moreover, the studies that used short mindfulness interventions for people with heart conditions received fewer drop outs (11 %) (Nyklíček et al., 2014; Olivo et al., 2009). This might indicate that a less demanding intervention in terms of course length could be more acceptable to this population. However, the length of course was discussed with our participants who completed the MBCT-HeLM and they agreed that 8 sessions was necessary to understand mindfulness and to be able to integrate into their daily lives, thus not agreeing with the idea of having a shorter course. Notably, in our study, the withdrawal and drops out rate was in between the initial recruitment and randomisation, with the most common reasons given relating health or job issues, rather than the intervention content.

The participants' adherence was high in terms of course completion, attendance at sessions and the long-day practice. However, it is important to note that the MBCT-HeLM acceptability could have been influenced by the fact that all the participants joined the study with stability regarding their CVDs. Consequently, future studies would need to target people with acute cardiac problems, such as people with a recent heart attack or stroke.

With regards to home practice, the participants reported a high amount of practice, however, most of found it difficult to allocate time to undertake it. The relationship between home mindfulness practice and outcomes has been examined in some prior research. For example, people with depression who spent more time on practice showed a lower relapse rate (Crane et al., 2014), lower rumination and depressive symptoms (Hawley et al., 2014) as well as higher mindfulness and well-being (Carmody and Baer., 2008), compared to people

who practised less. A similar picture also can be seen in studies targeting people with physical conditions (Rosenzweig et al., 2010). However, in our feasibility study, we did not examine effects of home practice on outcomes, thus future studies targeting comorbid depression in CVD populations would need to consider this issue.

Regarding assessment completion, the high rate that we had was relatively similar to those reported in studies by (O'Doherty et al., 2015; Olivo et al., 2009). This high rate, in addition to the small amount of missing data, indicated that the measures were acceptable to participants. However, some participants mentioned that some items did not apply to them, while others said that there were repetitive items in some measures.

Prior to the intervention started, most participants worried about being in a group and talking to new people or talking about personal issues (mental or physical problems, such as a heart attack or stroke). However, more a positive attitude developed throughout the course, including seeing the group as an opportunity to share personal experiences with others and helping them not to be introspective. Other qualitative studies in MBCT have reported a similar theme (Mason & Hargreaves, 2001).

In addition, making mindfulness practice a priority seemed to be a challenge for most of the participants in relation to allocating time to undertake the exercises and pushing themselves to keep practising. In the adapted manual, some of the exercises were shortened and efforts were made to make the course more flexible. However, this challenge seems not to be specific to physical populations. For example, a mindfulness research with recurrent depression has reported a similar challenge (Mann et al., 2016).

There was a diversity of participants' expectations in relation to joining the MBCT-HeLM, including help with heart conditions or high blood pressure, understanding depression, learning ways to feel calm and living the experience itself (mindfulness experience). In the psychotherapy field, it has been suggested that the initial expectations are

likely to have an impact on outcomes, including depression and anxiety disorders and participant's engagement with the intervention (Mason & Hargreaves, 2001; Webb, Kertz, Bigda-Peyton, & Björgevinsson, 2013). Hence, it would be useful to examine the role of expectations on outcomes in any future mindfulness studies for CVDs.

The 3-stage breathing space and body scan were found to be useful exercises for most of participants. Mindful movement seemed less helpful, as most of participants were old and suffering from other physical limitations. It is evident that high chronic physical symptoms are common in elderly populations (Naylor et al., 2012) and thus, this could be another barrier that should be considered in future trials. However, in a standard MBCT study (Foulk, Ingersoll-Dayton, Kavanagh, Robinson, & Kales, 2013) with older people with depression and anxiety, the participants showed high engagement with all the exercises and hence, the disengagement with some of MBCT-HeLM exercise, such as mindful movement, cannot be attributed to age only. One possible explanation might be that some people with cardiac problems have the misunderstanding that physical activity leads to worse cardiac outcomes (Klompstra, Jaarsma, & Strömberg, 2015; Rogerson, Murphy, Bird, & Morris, 2012). Hence, it would be useful to examine this issue using a qualitative method in future studies.

There were positive estimates of MBCT-HeLM usefulness. For example, means comparison regarding the primary outcome (depression) revealed that MBCT-HeLM and MBSR showed more benefits over TAU alone, with even better changes for MBCT-HeLM at the three months follow up. Additionally, the PHQ-9 clinical change indicated that both MBCT-HeLM and MBSR group were beneficial when compared to TAU. With regards to secondary outcomes, both MBCT-HeLM and MBSR showed more benefits compared to the TAU, indicating that a design with an active group, such as when using MBSR, would be a true test for MBCT-HeLM effects in future studies.

The relapse rate, as an outcome, was not examined in our study due to the feasibility constraints, however, any future definitive trial would need to include this to see whether MBCT-HeLM can help with protecting people with depression and CVDs from relapse comparing to an active group (e.g., MBSR). The HeLM feasibility study used MBSR, not standard MBCT, as comparator group for two reasons. First, MBSR was designed to help relieve pain and distress in people with chronic health problems (Kabat-Zinn, 1990, 2013), while MBCT, which combines meditation exercises and certain cognitive therapy techniques, was developed to target negative thinking styles in individuals with a history of depression, who are at a high risk of depressive relapse and recurrence (Segal, Williams & Teasdale, 2002, 2013). The comparison between adapted-MBCT and MBSR is important to achieve the objectives of the next phase of this project, aiming to determine the efficacy of an MBCT-HeLM on the treatment and prevention of depression. Another reason is in relation to mechanisms of action in MBCT and MBSR. MBCT addresses both universal vulnerabilities targeted by any mindfulness-based intervention, such as MBSR and specific ones implicated in depressive relapse (Crane et al., 2017). Thus, MBCT adaptations are intended to target more specifically the specific mechanisms that drive both depression and cardiovascular disorders (e.g., rumination and worry specific to CVD, lower self-efficacy and poor self-care) as well as the general mechanisms targeted by any mindfulness-based intervention (Alsubaie et al., 2017). As a result, it is hypothesised that such adaptations will enhance MBCT's acceptability and effectiveness compared with a more generic mindfulness-based intervention. One way to test this hypothesis is to compare MBCT adapted for CVD with a non-adapted mindfulness-based programme, such as MBSR. It is believed here that the use of standard MBCT as a comparator group would make it difficult to test the proposed common and specific mechanisms put forward and to prove that adapted-MBCT is capable of preventing relapse.

6.5.4 Some lessons learnt for the definitive trial.

The feasibility trial outcomes raise some important considerations that need to be taken into account for any future studies targeting CVDs with comorbid depression. First, the difficulties that were encountered in terms of recruiting people with depression and CVDs meant that conducting a definitive trial in the next phase may not be feasible. Hence, the suggestion put forward is to undertake a pilot RCT focusing on outcomes and resolving the issues around recruitment before carrying out a definitive trial, as suggested by Orsmond & Cohn, (2015). This may also help to focus more on differences between MBCT-HeLM and MBSR, which were not possible to explore in the feasibility trial, especially in relation to the relapse rate. We are aware of an equivalent definitive trial is currently being conducted in the US aimed at examining the effects of adapted MBSR for people with CVDs. It is anticipated that the findings of this trial will help to guide us in terms of whether we go ahead with a definitive trial or not.

Second, a better recruitment method, most likely involving multiple sites and over an extended period of time, is important to consider in the proposed RCT pilot. Third, the inclusion and exclusion criteria will need to be tightened in terms of those currently depressed (minor depression) or who have had a history of depression as well as the time since the cardiac event (heart attack or stroke) and depression onset (prior to or after a CVD). Fourth, it would be helpful to use an in-depth screening during the early stages of recruitment, which would capture the history of depression in detail, thereby increasing the eligibility rate. Fifth, an alternative method of determining cardiovascular disorder condition should be used, such as obtaining a clinical diagnosis from a potential participant's healthcare professional.

A critical issue to consider is the acceptability of adapted MBCT for people with depression and CVDs, given the high level of drop-out rate in this arm. A central aim of the

approach was to develop a tailored version of MBCT that would have high levels of acceptability for this population. It is known that high acceptability typically goes hand in hand with reduced drop-outs. Given incomplete information for reasons for drop out, it remains an open question as to whether high drop out in this trial does indeed sub-optimal acceptability of the intervention. Nevertheless, a number of suggestions can be made on the basis of the acceptability interviews. Firstly, participants expressed concern about being in a group or talking about personal issues. Secondly, the participants reported challenges associated with prioritising mindfulness practice in that they found it difficult to set aside adequate time to undertake the exercises. Furthermore, their expectations varied widely from gaining an understanding of depression to helping with high blood pressure and heart conditions. In the psychotherapy field, it has been suggested that the initial expectations are likely to have an impact on outcomes, including participant engagement with the intervention (Mason & Hargreaves, 2001; Webb, Kertz, Bigda-Peyton, & Björgvinsson, 2013). Another factor that could have contributed to high dropout is the considerable heterogeneity in the participants recruited into groups, with individuals varying in time since disease onset and also in the nature of disease (heart attack versus stroke). This may have reduced a sense of group cohesion and identification as the issues people were struggling with and their experiences of illness may have differed.

These issues should have equally affected both arms, however, and so cannot really account for the sub-optimal attrition in the MBCT arm. It does nevertheless suggest that any subsequent revisions of this approach should focus on building motivation to attend a group, ensuring people are at a point of life they can commit to the home practice, and ensuring they understand the focus of the approach. The orientation session is likely to be critical here. Moreover, it may be useful to consider reducing the home practice burden given participants are struggling with some current depression symptoms and are recovering from cardiac

disease. There is a trade-off here between acceptability and ensuring individuals receive a sufficient ‘minimum dose’ to benefit. Finally, it may be useful to either recruit a more homogeneous group of individuals (for example, just those who have suffered from a heart attack) or to adapt the course materials to more clearly pull out commonalities in experiences across conditions groups.

A more prosaic reason for drop out is that often there was a gap between participants being randomised and the start of treatment. In the interval between randomisation and treatment start, participant life circumstances may have changed. If they drop out in this phase, it may have nothing to do with perceived acceptability of MBCT. Future trials should consider robustly checking people availability and commitment prior to randomisation occurring. Also, the timing and locations of the groups may not have been optimal, for example being run in the day in a university setting. Further consultation with service user groups may help inform timing and location of the groups going forwards.

Given these concerns about adapted MBCT acceptability on the basis of high drop outs, it is important to acknowledge this remains a key unresolved uncertainty before moving towards a definitive trial. Further feasibility work is required to answer this issue before making the decision to move forwards with the next stage of the work.

6.6 The Strengths and Limitations of the PhD

To the best of my knowledge, this PhD is the first that has involved adapting MBCT for people with comorbid depression and CVDs. The adaptation of the manual was conducted systematically based on a phased approach suggested by the MRC and NIH. Throughout the project, there was cooperation with the public and patient group aimed at increasing the acceptability of the adapted MBCT. The feasibility study was conducted as an RCT with 3-arms and provided detailed data that can help with conducting any future trial. Moreover, when analysing and reporting the feasibility trial, there was adherence to the good practice

guidelines for designing, analysing and reporting pilot/feasibility studies. In addition, the qualitative study that assessed the acceptability provided information about the participant's experiences in relation to the course and study. The feasibility trial involved using measures that are not commonly deployed in the mindfulness field, including illness perception and cardiac anxiety level. These measures might help to uncover factors that have not received enough attention, despite having been associated with compliance and adherence to treatment.

However, the PhD has several limitations. First, the pilot group was designed as an uncontrolled with small sample size, thus any efficacy indicators should be taken with a high degree of caution. Second, the feasibility sample was heterogenous in terms of onset and types of depression and CVDs. Third, the HeLM high level of dropout rate should be considered as a significant limitation of the study as well as a potential sign that the tailored MBCT may not be more acceptable to people with CVDs and depression than standard MBCT or MBSR programmes. Fourth, in the feasibility trial, the assessor was not blind to the assessments at post intervention and follow up. In addition, the home practice was assessed only throughout the 8 MBCT sessions and therefore, the long-term effects have yet to be examined.

6.7 Future Research

As discussed in Chapter 2.0, very limited attention has paid to studying the common and specific mechanisms of MBCT for people with CVDs and hence, future studies will need to consider this issue. One possible mechanism that could be targeted is reactivity (physiological, cognitive and emotional) to stress that has been found to be associated with developing and progressing some CVDs (Carney et al., 1995; Key, Campbell, Bacon, & Gerin, 2008; Salomon, Clift, Karlsdóttir, & Rottenberg, 2009). The HeLM team had a plan to run a laboratory study aimed at assessing cognitive, emotional and physiological reactivity to

and recovery from a stress task in people with depression and CVDs who have or have not completed a mindfulness course. All the preparatory work for this study (i.e. the study protocol, ethics application form, stress task, recovery response and testing the procedures using four people from the PPI group) was completed over one year. However, the NHS ethics committee thought that the inclusion criteria should be tightened, which meant that recruiting enough people with depression and CVDs who had trained in mindfulness would be difficult. Consequently, the decision was made to drop this study.

Moreover, triangulating self-report, experimental and neuroscience methods would be helpful for targeting any common or specific mechanisms. Also, future studies would need to consider the Kazdin criteria carefully, which could help with improving the field of studying the mechanisms of mindfulness interventions. Moreover, it would be important for future studies to focus more on cardiac related outcomes, such as illness perceptions and cardiac anxiety, to uncover areas that are important to this population. Also, a more homogeneous sample regarding types and onset of CVDs and depression might help MBCT to target certain changes that can increase its effectiveness.

Importantly, the barriers addressed in the feasibility trial would need to be considered in any future studies aimed at increasing accessibility of a mindfulness intervention service for people with depression and CVDs. Some suggestions for improving such service for this population could be through delivering MBCT in the form of shorter or online courses. In addition, other barriers that might prevent people with such conditions from engaging with mindfulness interventions will need to be examined.

6.8 Summary of the PhD (HeLM Project)

This PhD, as a part of the Heart and Living Mindfully project, was aimed at developing a bespoke MBCT for people with depression and CVDs (MBCT-HeLM) through three phases. The first phase involved establishing the evidence base for the manual through

conducting a systematic review and secondary analysis. The second phase pertained to conducting a pilot group for modifying the manual and checking its acceptability. The third and last phase was a feasibility RCT to uncover uncertainties around the MBCT-HeLM before proceeding with a definitive trial. Overall, the three phases were successful and achieved their goals, despite the serious challenge in recruiting sufficient numbers of people. The feasibility RCT provided useful information for future studies in terms of using a 3-arm design, recruitment, attrition and retention.

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Appendices

Appendix A

Previous HeLM-Phases

HeLM Phase	Studies
Phase one (Basic research) 1. Analysis of AccEPT clinic data	Master thesis: First, we examined the efficacy and acceptability of MBCT/MBSR for people with depression and cardiovascular disorders in a routine clinical setting (Accept Clinic/Mood Disorder Centre) that formed my master's thesis. In this study, I analysed some of the AccEPT clinic dataset through early 2008 up until early 2013 using different methods, including pre-post intervention comparisons, the reliable change index (RCI) and clinically significant change (Cut-off), followed by benchmarking against randomised controlled trial studies. The study results showed that MBCT has potential effects in reducing depression and anxiety and improving the quality of life in people with depression and cardiovascular disorders.
Phase one (Basic research) 2. Systematic review	Second, two systematic reviews were conducted. The first was conducted by Abbott and colleagues (2014) to assess the effectiveness of mindfulness interventions (MBCT/MBSR) on vascular disorders. This review was published in September 2014 and indicated that MBCT and MBSR had small and medium effect sizes on stress, depression and anxiety, while their effects on medical outcomes, such as blood pressure, were mixed.
Phase two (Manual piloting) 1. First pilot group	The demographic characteristics of stakeholders who attended the first group as well as their retention and attendance rates are presented below. Demographic characteristics: 5 males and 3 females, six married, 8 white British, 3 employed and 3 retired, 8 with heart conditions. Completion rate: 4 completed and 4 did not. Attendance rate: four attended 6 or 8 sessions and four attended 2 or 3 sessions. Change in CVD criteria: After this group, the inclusion and exclusion criteria have updated and diabetes as a CVD removed. This change in criteria was decided upon following feedback from experts in cardiovascular disorders, who were of the opinion that diabetes has a different nature in terms of its symptoms and its impact on a person's life.

Appendix B

HeLM Systematic Review Forms

1. Keywords and example of Search strategy

Database Name:

Reviewer:

Date	Search term	Initial results	Cleaned results	Articles read	Potential related article	EndNote Exported
	mindfulness.					
	mbsr.					
	mbct.					
	(mindfulness and randomi*ed controlled trial*).ti,ab.					
	(mbsr and randomi*ed controlled trial*).ti,ab.					
	(mbct and randomi*ed controlled trial*).ti,ab.					
	(mindfulness and controlled trial*).ti,ab.					
	(mbsr and controlled trial*).ti,ab.					
	(mbct and controlled trial*).ti,ab.					
	(mindfulness and clinical trial*).ti,ab.					
	(mbsr and clinical trial*).ti,ab.					
	(mbct and clinical trial*).ti,ab.					
	(mindfulness and randomi*ed).ti,ab.					
	(mbsr and randomi*ed).ti,ab.					
	(mbct and randomi*ed).ti,ab.					
	(mindfulness and randomly).ti,ab.					

1. Keywords and example of Search strategy (cont.)

Database: Name:

Reviewer:

Date	Search term	Initial results	Cleaned results	Articles read	Potential related article	EndNote Exported
	(mbsr and randomly).ti,ab					
	(mbct and randomly).ti,ab					
	(mindfulness and randomi*ed efficacy trial*).ti,ab.					
	(mbsr and randomi*ed efficacy trial*).ti,ab.					
	(mbct and randomi*ed efficacy trial*).ti,ab.					
	(mbsr and randomi*ed controlled trial* and mechanism*).ti,ab.					
	(mbsr and randomi*ed controlled trial* and mediator*).ti,ab.					
	mbct and randomi*ed controlled trial* and mechanism*).ti,ab.					
	(mbct and randomi*ed controlled trial* and mediator*).ti,ab.					
	(mbsr and controlled trial* and mechanism*).ti,ab.					
	(mbsr and controlled trial* and mediator*).ti,ab.					
	(mbct and controlled trial* and mechanism*).ti,ab.					
	(mbct and controlled trial* and mediator*).ti,ab.					

1. Keywords and example of Search strategy (cont.)

Database Name:

Reviewer:

Date	Search term	Initial results	Cleaned results	Articles read	Potential related article	EndNote Exported
	(mbsr and clinical trial* and mechanism*).ti,ab.					
	(mbsr and clinical trial* and mediator*).ti,ab.					
	(mbct and clinical trial* and mechanism*).ti,ab.					
	(mbct and clinical trial* and mediator*).ti,ab.					
	(mbsr and randomi*ed and mechanism*).ti,ab.					
	(mbsr and randomi*ed and mediator).ti,ab.					
	(mbct and randomi*ed and mechanism*).ti,ab.					
	(mbct and randomi*ed and mediator).ti,ab.					
	(mbsr and randomly and mechanism*).ti,ab					
	(mbsr and randomly and mediator*).ti,ab					
	(mbct and randomly and mechanism*).ti,ab					
	(mbct and randomly and mediator*).ti,ab					
	(mbsr and randomi*ed efficacy trial* and mechanism*).ti,ab.					
	(mbsr and randomi*ed efficacy trial* and mediator).ti,ab.					

HeLM Systematic Review Forms (cont.)

2. Data extraction form

Reference ID:		Notes:
Author:		
Year:		
Journal:		
Country:		
Settings:		
Other		
Reviewer ID:		
Checked by:		

Theory and Hypotheses	
Aims of study	
Inclusion criteria	

HeLM Systematic Review Forms (cont.)

3. Characteristics of study based on PICOS

Population / participants		Intervention	Yes	No	Uncertain
Age:		MBCT			
Gender:	<input type="checkbox"/> Male <input type="checkbox"/> Female	MBSR			
		Is the intervention described as MBCT/MBSR?			
Sample size:		Is the duration of the intervention 8 weeks?			
No. of participants in intervention:		Has the intervention been adapted for the population studied?			
No. of participants in control group:		Home practice?			
Recourses of recruitment		Intervention was delivered by			
Notes					

Comparator		Outcomes		
No. of study arms:		Primary outcome:		
Type of intervention		Main results regarding the primary outcome.		
Type of control group:	<input type="checkbox"/> TAU <input type="checkbox"/> Waiting- list <input type="checkbox"/> Pharmacology <input type="checkbox"/> Active group* <input type="checkbox"/> Other*	Type of primary outcome:	<input type="checkbox"/> Psychological <input type="checkbox"/> Physical <input type="checkbox"/> QOL <input type="checkbox"/> Other	Notes:
Type of group if active or other? *		Secondary outcomes:		
		Main results of the secondary outcomes		
		Types of secondary outcomes:	<input type="checkbox"/> Psychological <input type="checkbox"/> Physical <input type="checkbox"/> QOL <input type="checkbox"/> Other	Notes:
Study design:	<input type="checkbox"/> RCT <input type="checkbox"/> CT			

HeLM Systematic Review Forms (cont.)

4. Mechanisms / mediators data:

No. of mechanisms / mediators assessed:	
Mechanisms / mediators assessed:	
Type of measures used in assessing mechanisms / mediators?	<input type="checkbox"/> Cognitive Task <input type="checkbox"/> Behavioural <input type="checkbox"/> Biological <input type="checkbox"/> Self-report <input type="checkbox"/> Interviewer administrated. <input type="checkbox"/> Other
Type of measures used in assessing outcomes?	<input type="checkbox"/> Cognitive Task <input type="checkbox"/> Behavioural <input type="checkbox"/> Biological <input type="checkbox"/> Self-report <input type="checkbox"/> Interviewer administrated. <input type="checkbox"/> Other
Assessment timeline of mechanisms	<input type="checkbox"/> Pre and post, not during <input type="checkbox"/> Only during <input type="checkbox"/> Pre, during and post <input type="checkbox"/> Pre and during (multiple assessments during intervention), not post <input type="checkbox"/> None <input type="checkbox"/> Other, specify: _____
Assessment timeline of outcomes	<input type="checkbox"/> Pre and post, not during <input type="checkbox"/> Only during <input type="checkbox"/> Pre, during and post <input type="checkbox"/> Pre and during (multiple assessments during intervention), not post <input type="checkbox"/> None <input type="checkbox"/> Other, specify: _____
Follow-up length (if applicable)	
Did the dose of MBCT/MBSR include at least 4 sessions?*	
Statistical analysis of mediators?	

HeLM Systematic Review Forms (cont.)

5. Assessment quality of studies

Mechanisms/mediators questions	Yes	No	Uncertain	Scores (Yes =1, no=0)	Note
Was the study guided by a theory?					
Are hypotheses about the mechanisms/mediators articulated?					
Did the study use measures to assess potential mechanisms / mediators?					
Can the design evaluate the mechanisms / mediators?					
- Making explicit that changes in processes are specifically targeted by the treatment					
- Occur during treatment?					
- Precede change in the outcome					
					Total of scores:

HeLM Systematic Review Forms (cont.)

6. Risk of bias in RCT

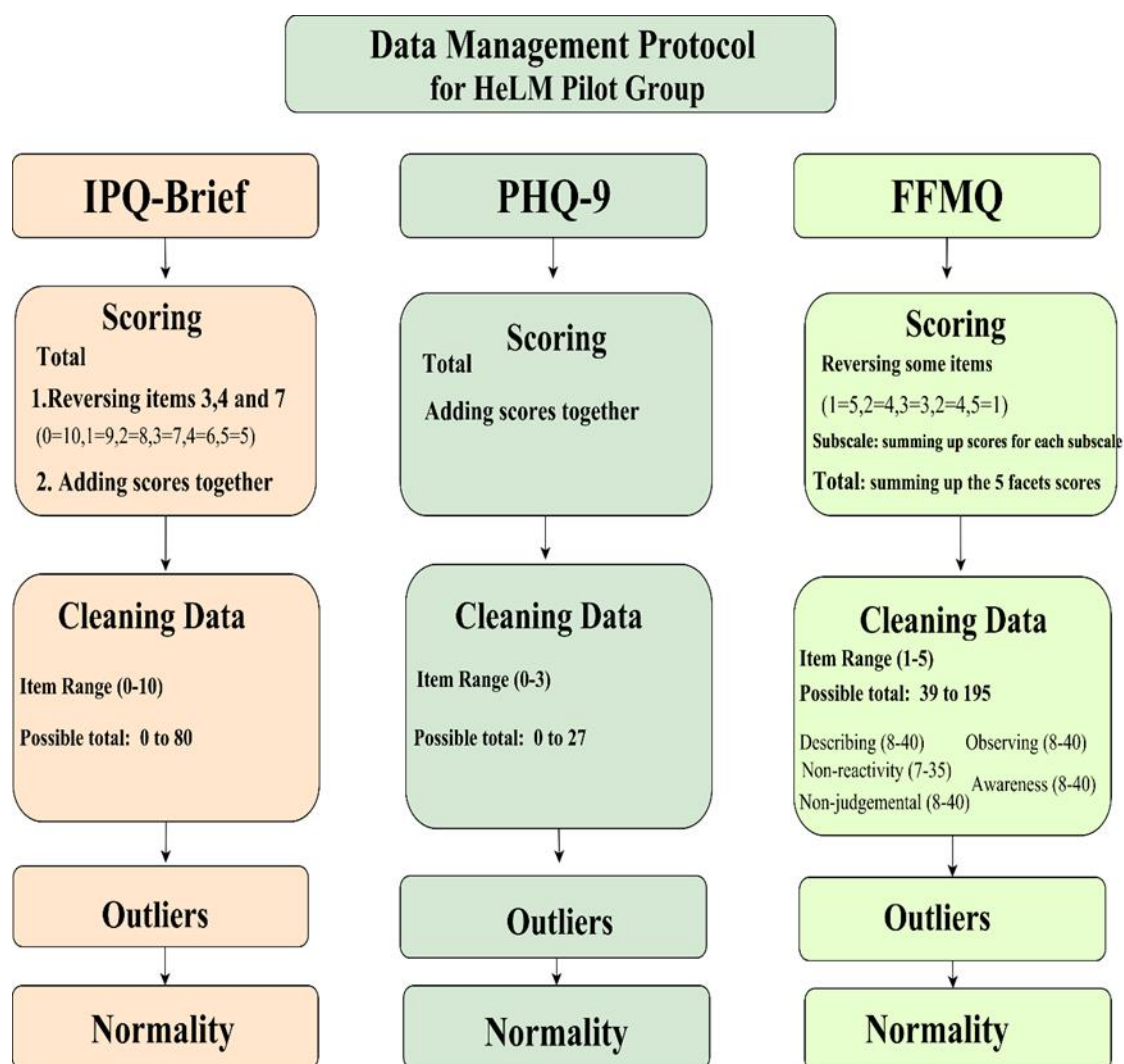
RISK OF BIAS (low risk, high risk, unclear, NA)	
Random sequence generation (if applicable)	
Notes	
Allocation concealment (if applicable)	
Notes	
Blinding of participants and personnel	
Notes	
Blinding of outcome assessment	
Notes	
Incomplete outcome data	
Notes	
Selective reporting	
Notes	

6. Risk of bias in RCT (cont.)

OTHER bias related aspects (Yes, No, Unclear)	
Eligibility criteria specified?	
notes	
Power calculations made/appropriate sample size?	
notes	
Baseline details similar and any imbalances adjusted for (if appropriate) ?	
Notes:	
Compliance with intervention?	
Notes:	
Data collection tools valid and reliable?	
Notes:	
All participants accounted for?	
Notes:	
Appropriate analyses?	
Notes –	
Other comments : ?	

Appendix C

Data Management Protocol for the HeLM Pilot Group



Appendix D1
HeLM Feasibility Poster

Heart and Living Mindfully (HeLM)

Do you have experience of a heart condition and of feeling low?

About the study

Mindfulness based treatments are already available on the NHS to help with problems such as stress, and emotional difficulties, including depression. We are aware that people with heart and circulation problems can also suffer from stress and other emotional difficulties.

We are conducting a study to see if a new course of Mindfulness-based Cognitive therapy (MBCT) specifically adapted for people with vascular disorders and low mood can help to manage their physical and mental well-being.

How it will help you

Your participation in this study would give you an opportunity to **learn new skills** that might help you **handling your illness better**.

If you are interested in participating or want to find out more, please contact Modi Alsubaie using the contact details below:

- **Tel:01392 726101**
- **Email: msfa202@exeter.ac.uk**

Appendix D2

Summary of Participants Information Sheet

Mindfulness-Based Cognitive Therapy For people with vascular disorders

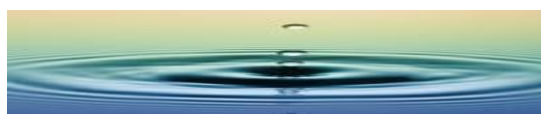


We are conducting a feasibility study to see if a new course of Mindfulness-based Cognitive Therapy (MBCT) can help people with vascular disorders (heart disease or stroke) and low mood to manage their physical and mental well-being.

We would like to invite you to take part in this study, called **Heart and Living Mindfully (HeLM)**.

What is MBCT for people with vascular disorders (heart disease or stroke)?

In an 8-week mindfulness course, people learn how to increase their focus on the present without worrying about the past or the future. We have adapted the course so that it addresses the sorts of issues people with vascular disorders have told us cause them to feel low or anxious.



Why have I been contacted?

You may have seen a poster or advertisement about this study, or a health professional you have been seeing has suggested that this study may be of interest to you because you have been experiencing some periods of low mood as well as vascular disorder (heart disease or stroke).

Do I have to take part?

No, taking part in this study is optional.

You have the right to refuse to participate or withdraw from the study at any time, without giving reasons.

Your participation in this study will not affect any routine care that you are currently receiving, nor will your care be affected if you decide at any stage to withdraw from this study.

What can I expect if I do take part in this study?

This is what will happen:

Summary of Participants Information Sheet (cont.)

1. We will need to gather some information about you. We will do this by asking you to attend an interview.
2. You will then be randomly allocated to one of three groups using a computer programme.
3. We will need to gather some information about you. We will do this by asking you to attend an interview.
4. You will then be randomly allocated to one of three groups using a computer programme.
 - a. **MBCT for people with vascular disorders (heart disease or stroke) + your usual care.** This is the 8-week mindfulness course specially adapted for people with vascular disorders;
OR
 - b. **Mindfulness - based stress reduction (MBSR) + your usual care.** This is the 8-week mindfulness course that is for people with a range of health problems, and not specifically adapted for people with vascular disorders;
OR
 - c. **The usual care alone.** That means, the care that you would normally receive if you were not taking part in this study
5. You will need to complete some self-report questionnaires at three different time points.
6. We will ask to measure your blood pressure at three different time points.
7. We will invite you again three months later, after completing the therapy to see how you are doing.

Will my participation in this study be kept confidential?

The collection of all data will be guided by the principle of strict confidentiality. Therefore, your name will not be found in any recording made or any questionnaire or form you complete. Your personal details will be stored safely and away from any collected data.

What will happen to the results of the research study?

All participants will be provided with a summary of all results once the study is completed. The results will be used to complete a part of the PhD studies of the lead researcher. It is possible that these results might be published as a part of an academic article or might be a part of presentation within an academic setting.

If you would like any further information, please contact:

Modi Alsubaie (Lead researcher), PhD student
School of Psychology, University of Exeter,
Exeter, EX4 4QG
Tel: 01392 726101, Email: msfa202@exeter.ac.uk

Appendix D3

Participants Information Sheet



Mindfulness-Based Cognitive Therapy

For people with Cardiovascular disorder

We are conducting a feasibility study to see if a new course of Mindfulness-based Cognitive Therapy (MBCT) can help people with cardiovascular disorders (heart disease or stroke) and low mood to manage their physical and mental well-being.

Mindfulness-based Cognitive Therapy (MBCT) is an 8-week course based on meditation that encourages people to be “in the present moment” and release the mind from negative ruminations that lead to worry, low mood and tiredness. The aim of MBCT is to increase awareness and choice and so enable more resilient responses to challenges. Living with vascular disorder (heart disease or stroke) is stressful, so developing ways to manage this stress can enable people to enjoy a good quality of life.

We would like to invite you to take part in this study, called Heart Living Mindfully (HeLM). However, before making a decision please read this information sheet carefully.

What is MBCT for people with vascular disorders (heart disease or stroke)?

In an 8-week mindfulness course, people learn how to increase their focus on the present without worrying about the past or the future. This is achieved through meditation exercises which help people become more aware of what is happening in their mind and body. Previously conducted studies have demonstrated that learning these mindfulness exercises can lead to positive effects on mood and quality of life.

We have adapted the course so that it addresses the sorts of issues people with vascular disorders have told us cause them to feel low or anxious.

What is the purpose of this study?

Low mood and anxiety are common amongst people with vascular disorders and are associated with poor long-term health. Mindfulness therapies have been found to have promising effects in reducing low mood. HeLM is an initial feasibility study where we are interested in finding out if adapted-MBCT may be helpful and acceptable for people with vascular disorders in reducing low mood, anxiety, fears and blood pressure.

Why have I been contacted?

You may have seen a poster or advertisement about this study, or a health professional you have been seeing has suggested that this study may be of interest to you because you have been experiencing some periods of low mood as well as vascular disorder.

Do I have to take part?

No, taking part in this study is optional. If you are interested in participating, then please feel free to ask any questions that you may have. You will then be asked to sign a consent form that gives us permission to collect and store the information that we have about you. **You have the right to refuse to participate or withdraw from the study at any time, without giving reasons.**

Participants Information Sheet (cont.)

Your participation in this study will not affect any routine care that you are currently receiving, nor will your care be affected if you decide at any stage to withdraw from this study.

What can I expect if I do take part in this study?

This is what will happen:

- 1- We will need to gather some information about you. We will do this by asking you to attend an interview.
2. You will then be randomly allocated to one of three groups using a computer programme.
 - a. **MBCT for people with vascular disorders + your usual care.** This is the 8-week mindfulness course specially adapted for people with vascular disorders;
OR
 - b. **Mindfulness - based stress reduction (MBSR) + your usual care.** This is the 8-week mindfulness course that is for people with a range of health problems, and not specifically adapted for people with vascular disorders;
OR
 - c. **The usual care alone.** That means, the care that you would normally receive if you were not taking part in this study

You will need to complete some self-report questionnaires at three different time points. . We will ask to measure your blood pressure at three different time points.

5. We will invite you again three months later, after completing the therapy to see how you are doing.

What information do you want to collect about me?

We will invite you to an initial interview at which we will gather information regarding your mental and physical health, both current and past. This will include any experiences of low mood and how this has impacted you. You will also be given the opportunity to ask any questions about this study. The interview will take between 30 to 45 minutes.

If following this interview and having had your questions answered, you are still interested in participating in this study, we will ask you to:

1. Read and sign the consent form.
2. Complete a set of questionnaires.
3. Allow us to measure your blood pressure.

The initial interview and assessments will normally be carried out at the University of Exeter, but we are happy to meet at other locations to suit your needs (e.g., your local GP surgery).

Completing the questionnaires and measuring your blood pressure will be done on three separate occasions:

1. Before you start therapy;
2. At the last session of the therapy;
3. Three months after completing the therapy.

Each time you complete an assessment with a researcher you will be given £10 as a token of appreciation for your participation in the study.

We would also appreciate it if you would give permission for us to record the interview on an audio tape. This will allow the researchers to be monitored to ensure that they are conducting the research according to the study protocol. If you do not want a recording to be made, you may inform the researcher of this at any time.

All recordings will be kept on a secure university hard drive or in a locked cabinet at the University of Exeter and accessed only by the researchers.

Why are there three groups in this study?

MBCT for people with vascular disorder is a new therapy so; we need to compare this therapy, with the standard mindfulness course and usual care. These comparisons will help us to know more about whether this new therapy is more helpful for people with vascular disorders than the other types of care.

Who will decide what group I will be in? (Adapted-MBCT, MBSR or usual care)?

After you have completed the initial interview and questionnaires, we will use a computer programme to randomly allocate one third of the participants to adapted MBCT, one third to MBSR and one third to the usual care.

The MBCT for people with vascular disorder group:

If you are allocated to this group, you will learn some meditation exercises plus certain cognitive therapy techniques and you will be asked to:

1. Attend one individual orientation session with your therapist to learn more about the therapy. This will take approximately one hour.
2. Attend 8 group sessions. These will be held on the same day of the week over 8 consecutive weeks. Each session will last for 2 hours and 15 minutes.
3. Practice daily for 30 min. We will provide you with CDs to help you in doing the practice.
4. Take part in two short interviews at two different time-points. Each of these will take approximately 20 minutes.

The standard MBSR group:

If you are allocated to this group, you will learn some meditation exercises and you will be asked to:

1. Attend one individual orientation session with your therapist to learn more about the therapy. This will take approximately one hour.
- 2- Attend 8 group sessions. These will be held on the same day of the week over 8 consecutive weeks. Each session will last for 2 hours and 15 minutes.
- 3- Practice daily for 45 min. We will provide you with CDs to help you in doing the practice.

The MBCT group and MBSR group will be run by trained therapists and will take place at the AccEPT Clinic at the University of Exeter.

We would like to video record the group sessions. These recordings will be used to make sure the therapists are doing a good job and will also be used to help train therapists in the future. If you are not happy with the video recordings being made, please inform the researcher about this.

It should be emphasised that any video recordings will be stored safely in a locked cabinet at the University of Exeter or on a password-protected hard drive and accessed only by the researchers.

Participants Information Sheet (cont.)

Usual care group:

As a member of this group, your routine care will continue unchanged and should you have any concerns or worries about your physical or mental health you should speak with either your GP or other health care professional who can advise of potential treatment options. After completing the study, you will be invited to take part in a standard MBCT course or MBSR course at the AccEPT Clinic at the University of Exeter if you would like to do so.

What are the possible disadvantages of taking part?

When participating, you will be asked to complete questionnaires and take part in interviews. There may be areas of a personal nature that some people might find uncomfortable to talk about. You do not have to discuss anything or answer any questions if you don't wish to do so.

What are the possible benefits of taking part?

Your participation will help us to explore whether adapted MBCT is feasible and acceptable to people with vascular disorders. If this is found to be the case, work will be able to continue to develop future MBCT groups for people suffering from vascular disorders.

What happens when the research study stops?

When the study is finished, you should discuss continuing your usual care with your health professional.

What if new information becomes available during the course of the study??

It is possible that during the course of this study, new information about the treatment we are studying will be discovered. In this case, you will be consulted, and you will be able to continue, or withdraw from the study.

If you decide to continue we will ask you to sign an updated consent form.

If you decide to withdraw we will inform your health professional so that you can make plans regarding the care you wish to receive.

In addition, if this information tells us that it is not good for you to continue in this study, we will inform you about this and advise you to discuss this situation with your health professional.

What if something goes wrong?

In case of any problems, we suggest you contact us without delay. If you were assigned to either the MBCT group or MBSR group, you can discuss any issue with the therapist leading the group or you can contact the lead researcher (please see details on the back page).

If you have anything which you would like to discuss with the lead researcher's supervisor, or the way in which the research has been done, you will also find appropriate details on the back page.

There is also the option to contact The National Health Service Complaints Mechanism (Patient Advice and Liaison Service) (Tel: **01392 402093**).

Will my participation in this study be kept confidential?

The collection of all data will be guided by the principle of strict confidentiality. Therefore, **your name will not be found in any recording made or any questionnaire or form you complete. Your personal details will be stored safely and away from any collected data.**

If you decide to participate in this study, we will seek your permission to contact your health professional to inform them that you are taking part, and which arm you are allocated to.

If during the course of the study, information revealed that you were at significant risk of harm to yourself or others this information will be discussed with your health professional but normally only

Participants Information Sheet (cont.)

after discussion with you.

What will happen to the results of the research study?

All participants will be provided with a summary of all results once the study is completed. The results will be used to complete a part of the PhD studies of the lead researcher. It is possible that these results might be published as a part of an academic article or might be a part of presentation within an academic setting.

We will ensure the privacy and confidentiality of your personal information. Any publications or presentations arising from this study will not contain any information which would allow you to be identified as a participant.

If you would like any further information, please contact:

Modi Alsubaie (Lead researcher)

PhD student

The Mood Disorders Centre

School of Psychology

University of Exeter,

EX4 4QG

Tel: 01392 726101

Email: msfa202@exeter.ac.uk

Alternatively, you may contact the Lead

Researcher's Supervisor:

Willem Kuyken

Professor of Clinical Psychology

Co-director Mood Disorders Centre

Tel: 01392 724659

EX4 4QG

Email: w.kuyken@exeter.ac.uk

Appendix E

SCID Baseline Template Score Sheet

<u>A. MOOD EPISODES</u>					
<u>CURRENT MAJOR DEPRESSIVE EPISODE in Past month</u>					
1.	Depressed or down (2 wks+)	?	1	2	3
	and / or				
2.	Loss interest/ pleasure (most activities/day).	?	1	2	3
**IF NEITHER IS CODED "3" SKIP TO A12 (PAST MDE)					
3.	Weight change (increased / decreased)	?	1	2	3
4.	Sleep change (insomnia / hypersomnia)	?	1	2	3
5.	Psychomotor agitation/retardation	?	1	2	3
6.	Fatigue/low energy	?	1	2	3
7.	Worthlessness/Guilt (NB excessive or inappropriate) ?	1	2	3	
8.	Concentration (thinking/indecisiveness)	?	1	2	3
9.	Suicide	?	1	2	3
Thought of own death __ Suicidal ideation __ Specific Plan __ Suicide attempt__					
Five sx's coded "3", and at least one of these is item 1 or 2. 1			3		
(CRITERION B HAS BEEN OMITTED FROM SCID)					
C. Functional Impairment		?	1	2	3
**IF CODED 1 GO TO A12 (PAST MDE)					
D. Not Due to General Medical Condition/ Substance abuse		?	1		3
**GO TO A43 TO CHECK IF NECESSARY					
E. Recent Bereavement		?	1		3
**IF EITHER D or E 1 GO TO A12 (PAST MDE)					
=>MDE IF A, C, D, AND E ARE CODED "3"			1	3	
Total No of MDEs (including current) _____ (CODE 99 if too many or indistinct)					
CURRENT MDE SPECIFIERS					
WITH POSTPARTUM ONSET (A6)			1		3
WITH CATATONIC FEATURES (A6-A7)			1	3	
WITH MELANCHOLIC FEATURES (A8-A9)			1		3
WITH ATYPICAL FEATURES (A10-A11)			1	3	
**IF Past Major Depressive Episode/s GO TO A12 otherwise GO TO A1					

SCID Baseline Template Score Sheet (cont.)

PAST MAJOR DEPRESSIVE SYNDROME

A

- | | | | | |
|---|---|---|---|---|
| 1. Depressed or down (2 wks+) | ? | 1 | 2 | 3 |
| 2. Less interest/pleasure (most activities/day) | ? | 1 | 2 | 3 |

****IF A1 / A2 = 1 GOTO A18 – Current Manic**

Most recent if in last year OR Worst ever episode if over 1 year

- | | | | | |
|--|---|---|---|---|
| 3. Weight change (increased / decreased) | ? | 1 | 2 | 3 |
| 4. Sleep change (insomnia / hypersomnia) | ? | 1 | 2 | 3 |
| 5. Psychomotor agitation/retardation | ? | 1 | 2 | 3 |
| 6. Fatigue/low energy | ? | 1 | 2 | 3 |
| 7. Worthlessness/Guilt | ? | 1 | 2 | 3 |
| 8. Concentration (thinking/indecisiveness) | ? | 1 | 2 | 3 |
| 9. Suicide | ? | 1 | 2 | 3 |

Thought of own death __ Suicidal ideation __ Specific Plan __ Suicide attempt __

Five sx's coded "3", and at least one of these is item 1 or 2. 1 3

(NB: B Criteria not included in the SCID)

C. Functional Impairment

? 1 2 3

****IF CODED 1 & there was a worst time GO BACK TO A12 and do 'worst' / 1 & no worst time goto A18**

D. Not Due to General Medical Condition/ Substance abuse

? 1 3

****GO TO A43 TO CHECK IF NECESSARY**

E. Recent Bereavement

? 1 3

Age of onset of Past MDE _____

Total No of MDEs (including current) _____ (CODE 99 if too many or indistinct)

(For recording more past MDEs go to J9)

Results of SCID Form

Participant ID:

Interviewer.....

Date:

Vascular disorder	Current MDE	Past MDE
Dysthymia	Minor depression	Notes
Impression: 1. 2. 3. 4. 5.		

Appendix F

HeLM Participants Consent

		yes	No
1.	I have read and understood the information sheet dated 07/05/2014 (version1.2) for the above study and have been given a copy to keep.		
2.	I have had the opportunity to consider the information and ask any questions.		
3.	I have received enough information about the study.		
4.	I agree to take part in the above study		
5.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care being affected.		
6.	I understand that details of my participation will be stored anonymously on file and may be used in the final analysis of data.		
7.	I agree to the interviews and therapy sessions being audio and video recorded for the purposes of therapy, supervision, assessment and feedback for therapists.		
8.	I agree to my recordings being used for training purposes. I understand that the trainers would be staff and students of the University of Exeter bound by their professional codes of conduct.		
9.	I understand that I may order the recordings to be destroyed when my therapy is complete if I do not wish them to be used for research/training purposes.		
10.	I agree to my GP/Health professional being informed of my participation in this study and being updated with information relevant to my medical care.		
11.	I agree to my contact details being added to the Mood Disorders Centre's database so that I might be invited in the future to take part in other depression research.		

When you have initialled all the boxes above, please complete below including the date yourself.

Name of participant
(BLOCK CAPITALS)

Date

Signature

I have explained the study to the above patient and he/she has indicated his/her willingness to take part in the study.

Name of Researcher
(BLOCK CAPITALS)

Date

Signature

Appendix G1
HeLM Feasibility Screening Form (1)

INTERVIEWER DETAILS		
Interviewer: _____	Date of screening interview: ____/____/____	
Duration of call Start time: _____ End time: _____	Referrer _____ Referral date: _____	
SECTION 1a : PARTICIPANT INFORMATION (check correct) MDC Number : _____		
Forename _____ Surname _____ Pref name _____		
Title <input type="checkbox"/> Mr <input type="checkbox"/> Mrs <input type="checkbox"/> Miss <input type="checkbox"/> Ms <input type="checkbox"/> Other _____		Gender <input type="checkbox"/> Male <input type="checkbox"/> Female
DOB: / /	GP _____	Surgery _____
SECTION 1b : PARTICIPANT CONTACT DETAILS		
Main contact details Address _____ _____ Telephone numbers Home number _____ Preferred time: _____ Mobile _____ Preferred time: _____ Work number _____ Preferred time: _____ Is it OK to leave a message on the answer phone? _____ E-mail address Main e-mail _____		
Alternative contact details Address _____ _____ Telephone numbers _____ E-mail address _____		

HeLM Feasibility Screening Form (1) (cont.)

SECTION 1c: Formal Concurrent Psychotherapy	
Currently in therapy/counselling <input type="checkbox"/> Yes (<i>Ask questions below</i>) <input type="checkbox"/> No <i>If currently in therapy/counselling:</i> Type of therapy _____ Duration of therapy _____ Will have finished therapy by _____	
SECTION 2: Inclusion Criteria MDC number: _____	
2.1 Experience of Depressive Episode:	
Have you ever experienced depression/ low mood* <input type="checkbox"/> Yes <input type="checkbox"/> No Details: _____ _____ _____ *Assess this by listing symptoms if necessary – collect information Circumstances with Depression: <i>Did you need to go to the GP</i> <input type="checkbox"/> Yes <i>Are you or have you taken medication for it</i> <input type="checkbox"/> Yes <i>Any other help?</i> <input type="checkbox"/> Yes Details: _____ _____ Number of previous episodes (self-report) _____	
2.2. Current Depressive Episode (exclusion criteria):	
<input type="checkbox"/> Yes <input type="checkbox"/> No since (approx. time) _____	
<i>In past month:</i> <input type="checkbox"/> Depressed mood or feeling down <input type="checkbox"/> Two weeks or more	<i>In past month:</i> <input type="checkbox"/> Diminished interest/pleasure most activities/days <input type="checkbox"/> Two weeks or more
<i>Sleep change:</i> <input type="checkbox"/> Insomnia <input type="checkbox"/> Hypersomnia Score:	<div style="display: flex; justify-content: space-between;"> <div> <i>Significant weight change:</i> <input type="checkbox"/> Loss <input type="checkbox"/> Gain Score: </div> <div> <i>Significant appetite change:</i> <input type="checkbox"/> Loss <input type="checkbox"/> Gain </div> </div>

<i>Psychomotor change:</i> <input type="checkbox"/> Agitation <input type="checkbox"/> Retardation Score:	<i>Energy level change:</i> <input type="checkbox"/> Fatigue <input type="checkbox"/> Low energy Score:
<i>Feelings about self:</i> <input type="checkbox"/> Guilt <input type="checkbox"/> Worthlessness Score:	<i>Concentration problems:</i> <input type="checkbox"/> Thinking <input type="checkbox"/> Indecisiveness Score:
<i>Hopeless/Suicide</i> <input type="checkbox"/> Feeling hopeless or suicidal → <input type="checkbox"/> Feeling persists <input type="checkbox"/> Considered self-harm → <input type="checkbox"/> Did self-harm Score:	Concern patient is suicidal and has unmet needs <input type="checkbox"/> Yes <input type="checkbox"/> No

3. Heart Conditions – Vascular disease (Inclusion criteria)

Do you currently suffer with a heart condition or vascular disease? ☐ Yes ☐ No

Which of the following; *Tick and circle appropriate*

Coronary heart disease (angina, myocardial infarction – heart attack- and stroke) ☐

Peripheral vascular disease (poor circulation in the legs / hands) ☐

Diabetes ☐

Hypertension (high blood pressure) and hypercholesterolemia (raised cholesterol) ☐

Experienced a cardiac condition or event; heart attack, by-pass surgery, angina, angioplasty or stents ☐

Notes:

SECTION 4: Exclusion Criteria		MDC number _____
4.1. Alcohol Use Ever caused a problem for you <input type="checkbox"/> Yes <input type="checkbox"/> No Current use is a problem <input type="checkbox"/> Yes <input type="checkbox"/> No Friends comment on use/ Attended AA meeting?	4.2. Drug Use Ever caused a problem for you <input type="checkbox"/> Yes <input type="checkbox"/> No Current use is a problem <input type="checkbox"/> Yes <input type="checkbox"/> No Friends comment on use/ Attended NA meeting?	
4.3. Current Psychosis (SCREEN Questions)		<input type="checkbox"/> Yes <input type="checkbox"/> No
Previous Diagnosis of Mental Health Problems <div style="display: flex; justify-content: space-between;"> <div>Diagnosis – Manic-Depression</div> <div><input type="checkbox"/> Yes <input type="checkbox"/> No</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Diagnosis – Bipolar Disorder</div> <div><input type="checkbox"/> Yes <input type="checkbox"/> No</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Ever been diagnosed with any other mental health problem</div> <div><input type="checkbox"/> Yes <input type="checkbox"/> No</div> </div> <div style="display: flex; justify-content: space-between;"> <div>If Yes, what: _____</div> <div>Exclusion ? <input type="checkbox"/> Yes <input type="checkbox"/> No</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Ever cut, burnt or otherwise injured yourself deliberately</div> <div><input type="checkbox"/> Yes <input type="checkbox"/> No</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Suggestion of psychosis on screen (→ APPENDIX C: PSQ)</div> <div><input type="checkbox"/> Yes <input type="checkbox"/> No</div> </div> <div style="margin-top: 10px;"> Further information _____ </div>		

Eligible?	Interested?	Can do group dates?
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ORIENTATION APPOINTMENT

Date: _____

With: _____

Psychosis Screening Questionnaire

Temp ID number

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I have to ask about a whole range of experiences. Some of these experiences are quite rare. However, I would be very grateful if you would bear with me and answer the questions I am going to ask you now.

		Yes	No	Unsure
Q1	Have there ever been times when you felt very happy indeed without a break for days on end?	1 → (a)	2 → Q2	3 → Q2
	(a) Was there an obvious reason for this?	1 → Q2	2 → (b)	3 → Q2
	(b) Did your relatives or friends think it was strange or complain about it?	1 → Screen +	2 → Q2	3 → (b)
Q2	Have you ever felt that your thoughts were directly interfered with or controlled by some outside force or person?	1 → (a)	2 → Q3	3 → Q3
	(a) Did this come about in a way that many people would find hard to believe, for instance, through telepathy?	1 → Screen +	2 → Q3	3 → Q3
Q3	Have there ever been times when you felt that people were against you?	1 → (a)	2 → Q4	3 → Q4
	(a) Have there been times when you felt people were deliberately trying to harm you or your interests?	1 → (b)	2 → Q4	3 → Q4
	(b) Have there been times when you felt a group of people was plotting to cause you serious harm or injury?	1 → Screen +	2 → Q4	3 → Q4
Q4	Have there ever been times when you felt that something strange was going on?	1 → (a)	2 → Q5	3 → Q5
	(a) Did you feel it was so strange that other people would find it hard to believe?	1 → Screen +	2 → Q5	3 → Q5
Q5	Have there ever been times when you heard or saw things other people couldn't?	1 → (a)	2 → End	3 → End
	(a) Did you at times hear voices saying quite a few words or sentences when there was no one around that might account for it?	1 → Screen +	2 → End	3 → End

If + screening for Psychosis (Q2-Q5): Check whether Sx are associated with depression:

- About the difficulties you have just described, did these happen only when you were depressed or at other times? ☐ Depression with psychotic features ☐ Psychosis

Appendix G2

HeLM Feasibility Screening Form (2)

HeLM Telephone Screening Form/Part2	
Interviewer: _____	Date of screening interview: ____/____/____
<i>Duration of call</i> Start time: _____ End time: _____	HeLM research number: _ _ _ _ _
3.2 Current Depressive Episode* (exclusion criteria): <input type="checkbox"/> Yes <input type="checkbox"/> No since (approx. time) _____	
<i>In past month:</i> <input type="checkbox"/> Depressed mood or feeling down <input type="checkbox"/> Two weeks or more	<i>In past month:</i> <input type="checkbox"/> Diminished interest/pleasure most activities/days <input type="checkbox"/> Two weeks or more
<i>Sleep change:</i> <input type="checkbox"/> Insomnia <input type="checkbox"/> Hypersomnia Score: _____	<i>Significant weight change:</i> <i>Significant appetite change:</i> <input type="checkbox"/> Loss <input type="checkbox"/> Gain <input type="checkbox"/> Loss <input type="checkbox"/> Gain Score: _____
<i>Psychomotor change:</i> <input type="checkbox"/> Agitation <input type="checkbox"/> Retardation Score: _____	<i>Energy level change:</i> <input type="checkbox"/> Fatigue <input type="checkbox"/> Low energy Score: _____
<i>Feelings about self:</i> <input type="checkbox"/> Guilt <input type="checkbox"/> Worthlessness Score: _____	<i>Concentration problems:</i> <input type="checkbox"/> Thinking <input type="checkbox"/> Indecisiveness Score: _____
<i>Hopeless/Suicide</i> <input type="checkbox"/> Feeling hopeless or suicidal persists → <input type="checkbox"/> Feeling <input type="checkbox"/> Considered self-harm → <input type="checkbox"/> Did self-harm Score: _____	Concern patient is suicidal and has unmet needs <input type="checkbox"/> Yes <input type="checkbox"/> No

*PHQ-9 Score: (0) not at all – (1) several days – (2) More than half the days – 3 (Everyday)

HeLM Feasibility Screening Form (2) (cont.)

3.3 Exclusion Criteria

Alcohol Use

Ever caused a problem for you ☐ Yes ☐ No

Current use is a problem ☐ Yes ☐ No

Friends comment on use/ Attended AA meeting?

Drug Use

Ever caused a problem for you ☐ Yes ☐ No

Current use is a problem ☐ Yes ☐ No

Friends comment on use/ Attended NA meeting?

Eligible for baseline interview?

Interested?

Can do group dates?

Baseline assessment appointment

Date: _____

With: _____

Telephone Screening Interview Script/ part 1

HeLM PROJECT for cardiovascular disorders and Heart conditions

Introduction;

My name is _____ and I'm calling from University of Exeter. I'm calling because you recently expressed an interest in taking part in a study for people with vascular disorders and I am just phoning to follow that up. Is this a convenient time to call?

Purpose of phone call:

Explain a little more about the project, give you a chance to ask any questions that you may have and perhaps ask you some questions to see if our study right for you or not.

Would that be ok to do now? It will take about 10/15 minutes in all.

I am gonna tell you a little bit about the study:

We are conducting a small study to see if a new course of Mindfulness-based Cognitive Therapy (MBCT) can help people with heart disease or stroke and low mood to manage their physical and mental well-being.

In this study, we will have three groups. The first group will be the new course of mindfulness which was adapted especially for people with heart diseases/stroke.

The second group is a standard mindfulness course which has been widely used with people with pain and other chronic disorders and the third group will be the usual care; this means you will continue your routine care and you will not receive any therapy.

The reason behind having three groups in this study is because MBCT for people with heart disease/stroke is a new therapy and so we need to compare this therapy with the other forms that are already available. These comparisons will help us to know more about whether the new MBCT therapy is more helpful for people with vascular disorders than the other types of care.

We will use a computer programme to randomly allocate you to one of the three groups. We need 30 pts, this means 10 participants will allocate to the new course, 10 participants will allocate to the other mindfulness course and 10 participants will allocate to the usual care. If you allocated to the usual care, after finishing the study, we would invite you to attend the standard mindfulness courses that are available at the clinic at the University of Exeter.

Do you have any questions at this point?

It may just be helpful if I tell you a little bit about mindfulness. Do you know much about it or are you familiar with it at all?

If no, mindfulness is a form meditation therapy made up of a number of different practices as well as learning different ways to bring your awareness into the everyday activities in life.

So based on the information I have just given you does this sound like something you are potentially interested in taking part in?

If no, Ok, well thank you for your time and interest in the study, it has been great speaking to you. END.

If yes, great, what I would like to do now is ask you some questions. Is now a convenient time?

Some of the questions I will ask will involve you giving personal information about your medical and psychological history, is that ok?

Before I start with the questions it may be worth checking that you are able to attend the group dates first. The groups will be next Feb and March, every Tues or Wed between 10 am to 12:30 pm. Are you able to attend those dates?

Great, now I'm gonna start with the questions but at any point you want to stop or don't want to answer the question please just say.

SECTION 1: Participant Information / Contact Details

"To begin with, I'd like to check that we have your information correct and also to ask you a few further questions about yourself."

- 1) "Can you confirm that your surname is _____ and your first name is _____? Do you have a different preferred name?"
- 2) "What is your title?"
- 3) "Please can you tell me your age and your date of birth?"
- 4) Please could you give me your GP's name and address?"
- 5) "What is your postal address?"
- 6) "Please can you provide me with your home telephone number and your mobile number? Do you have any other contact numbers for you that may be useful to us?"
 "Is it okay to leave a message on that/on your house phone?"
 "Where are you now "if calling mobile".
 "Do you have a preferred time for us to call you?"
- 7) "Do you have an email address?"

Formal concurrent psychotherapy

- 1) "Are you currently receiving any other type of therapy or are you currently seeing a counsellor?"
 (If YES: "What type of therapy are you receiving?"")
 (If YES: "When did you roughly start this therapy?" "Do you have plans to finish the therapy over the next 6 months?"")

Section 2: Inclusion Criteria

2.1. Experience of Past Depressive Episode

"I'd like to ask you some questions about depression and low mood if that's ok.

- 1) Is depression or low mood something you experience?

If yes, could you tell me a bit more about that?

(If need prompting) If I list a number of symptoms usually associated with low mood, could you perhaps tell me if they are something you experience and to what extent? List symptoms, get further information.

- 2) Have you previously experienced other episodes of low mood and/or depression?

If yes, are you able to say approx. how many?

2.2. Vascular disorder

- 1) Do you currently suffer from a vascular disorder or heart condition?
 (If YES)

- 2) Could you tell me what type of heart condition?
- 3) Would you mind telling me a little bit more about that? *Here we are looking for experience, how it affected them, when it happened, problems they face etc.*

(If NO, go to the not currently eligible section)

SECTION 3: Exclusion Criteria

3.1 Previous Diagnosis of Mental Health Problems

- 1) “Have you ever been diagnosed with bipolar disorder or manic depression?”
- 2) “Have you ever been diagnosed with any other mental health condition?”
See appendix C: Past Manic Episode Questions.
- 3) “Have you ever cut, burnt, or otherwise injured yourself deliberately?”
(If YES: “When was the last time you cut/burnt/injured yourself deliberately?”)
(If YES: “Are you currently receiving therapy for your self-harming?”)

3.2. Ability to engage with MBCT /MBSR

“Well that’s the end of the questions but what I’d now like to do is tell you a little bit about taking part in MBCT OR MBSR.

“Taking part in MBCT OR MBSR can be quite demanding in terms of the time involvement both during the classes and outside of classes. For example, there will be 2 hour classes each week for 8 weeks, and there will be homework which is typically 40-60 minutes a day, 6 days a week over the 8 week course. Some of the exercises that participants will do in the class may also involve very gentle stretching or moving, or sitting still for periods of time. So, some individual exercises may last between 30-40 minutes. However, not *all* exercises will be this long.”

“Does MBCT OR MBSR sound like something that you’d be willing to engage with?”

If Not Currently Eligible:

“Thank you for taking the time to speak to me today. As I mentioned earlier we can only offer people places on the research trial if they meet certain criteria. This is because we are trying to make it a fair scientific test and need to control certain factors such as whether people are currently depressed or are in another form of therapy. I am sorry but cannot offer you a place on the trial as you do not currently meet the criteria that we are looking for. This is because (*SELECT APPROPRIATE: you haven’t experienced depression/low mood -you are not able to engage with MBCT/MBSR...*)

If Currently Eligible:

“Thank you for providing this information. Based on this information you have given me so far it sounds like you meet the criteria for our study so what I would like to do is call you again in October to ask some further questions to make absolutely sure that the study is right for you. Explain here that due to the group being a little while away there are some questions that we cannot ask right now.

Does that sound ok to you?

“Finally, do you have any questions that you’d like to ask me about the study? I’ll give you my telephone number in case you have any questions in the meantime and please feel free to call me any time.

Thank you for your time today and for answering these questions, speak to you in a few months.

Appendix H

HeLM feasibility - stratification

	Research ID	Type of vascular disorders	Severity of depression based on PHQ-9*	Total PHQ-9
1		Heart condition	Minimal depression	1
2		Heart condition	Moderate depression	10
3		Heart condition	Moderate depression	14
4		Heart condition	Minimal depression	0
5		Stroke	Mild depression	5
6		Heart condition	Moderate depression	12
7		Hypertension	Moderately severe depression	15
8		Hypertension	Minimal depression	4
9		Heart condition	Mild depression	6
10		Heart condition	Moderately severe depression	15
11		Heart condition	Mild depression	9
12		Stroke	Minimal depression	2
13		Stroke	Minimal depression	4
14		Stroke	Mild depression	7
15		Hypertension	Mild depression	9
16		Heart condition	Moderate depression	14
17		Heart condition	Moderate depression	10
18		Heart condition	Moderately severe depression	17
19		Heart condition	Moderately severe depression	18
20		Heart condition	Mild depression	7
21		Stroke	Moderate depression	12
22		Stroke	Moderately severe depression	19
23		Stroke	Mild depression	6
24		Stroke	Moderately severe depression	16
25		Heart condition and stroke	Moderate depression	10
26		Heart condition	Minimal depression	3
27		Heart condition	Minimal depression	2
28		Hypertension	Mild depression	7
29		Heart condition	Mild depression	6
30		Heart condition	Moderately severe depression	16
31		Stroke	Mild depression	9
32		Heart condition	Mild depression	9
33		Heart condition	Mild depression	6

HeLM groups (MBCT-HeLM, MBSR, and TAU).

Type of cardiovascular disorders (Heart condition, Stroke and Hypertension).

Severity of depression based on PHQ-9 (0-4 Minimal Depression, 5-9 Mild Depression, 10-14 Moderate Depression, 15-19 Moderately severe Depression, 20-27 Severe Depression).

Appendix I

HeLM Feasibility measures

1. Background information

The purpose of this questionnaire is to obtain some information about your background, which may be relevant to your situation. Any information you provide is strictly confidential.

1.

Research Number	
Date of birth	
Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female
Occupation	
Education	
Religion	
Ethnic group	White / Mixed / Asian or Asian British / Black or Black British / Chinese or Other Ethnic Group
Marital Status	<input type="checkbox"/> Single <input type="checkbox"/> Married or living together <input type="checkbox"/> Separated or divorced <input type="checkbox"/> Widowed
Email	
GP name	
GP Surgery	
How frequently do you see you GP?	

2. What type of vascular disorders (heart conditions/ stroke/ hypertension) do you suffer from?

- If you suffer from a heart condition, please specify further what type of heart condition?

3. Do you suffer from other medical conditions?

- ☐ Yes ☐ No If yes, please specify further:

4. Are you aware of any physical illness or other limitations that may make hearing, sitting, standing, walking, or doing simple exercises difficult for you

- ☐ Yes ☐ No

If yes, please specify further:

5. Are you taking any medications (prescribed and non-prescribed) at the moment?

- ☐ Yes ☐ No

If yes, please list in the table below

Medications	Dosage	Frequency	Reason
-------------	--------	-----------	--------

1.			
2.			
3.			
4.			
5.			
6.			
7.			

6. Are you currently receiving any therapy/counselling / support regarding your medical condition?

☐ Yes

☐ No

If yes, please specify further:

7. Are you taking any medications for depression?

☐ Yes

☐ No

If yes, please specify further

8. Have you ever received psychiatric or psychological treatment before?

☐ Yes

☐ No

If yes, please specify:

9. Are you currently receiving any therapy\ counselling \ support regarding your mental health?

☐ Yes

☐ No

If yes, please specify further

2. Patient Health Questionnaire

Research Number Date completed.....

Over the last 2 weeks , how often have you been bothered by any of the following problems? (Use “ ✓ ” to indicate your answer”	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things.	0	1	2	3
2. Feeling down, depressed, or hopeless.	0	1	2	3
3. Trouble falling or staying asleep or sleeping too much.	0	1	2	3
4. Feeling tired or having little energy.	0	1	2	3
5. Poor appetite or overeating.	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down.	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television.	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual.	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way.	0	1	2	3
	Total Score: Level:			

3.Generalised Anxiety Disorder-7

Research Number Date completed.....

Over the <u>last 2 weeks</u> , how often have you been bothered by any of the following problems	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Having trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid that something awful might happen	0	1	2	3
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Total Score	<input type="text"/>		
	Level	<input type="text"/>		

4.Cardiac Anxiety Questionnaire

Research Number: Date completed.....

The following lists behaviours that people may do if they are worried about their heart problems. Please rate each item by circling the answer (number) that applies to you.

		Never	Rarely	Sometimes	Often	Always
1	I pay attention to my heart beat.	0	1	2	3	4
2	I avoid physical exertion.	0	1	2	3	4
3	My racing heart wakes me up at night.	0	1	2	3	4
4	Chest pain/ discomfort wakes me up at night.	0	1	2	3	4
5	I take it easy as much as possible.	0	1	2	3	4
6	I check my pulse.	0	1	2	3	4
7	I avoid exercise or other physical work.	0	1	2	3	4
8	I can feel my heart in my chest.	0	1	2	3	4
9	I avoid activities that make my heart beat faster.	0	1	2	3	4
10	If tests come out normal, I still worry about my heart.	0	1	2	3	4
11	I feel safe being around a hospital, physician or other medical facility.	0	1	2	3	4
12	I avoid activities that make me sweat.	0	1	2	3	4
13	I worry that doctors do not believe that my symptoms are real.	0	1	2	3	4

When I have chest discomfort or when my heart is beating fast:

		Never	Rarely	Sometimes	Often	Always
14	I worry that I may have a heart attack.	0	1	2	3	4
15	I have difficulty concentrating on anything else.	0	1	2	3	4
16	I get frightened.	0	1	2	3	4
17	I like to be checked out by a doctor.	0	1	2	3	4
18	I tell my family or friends.	0	1	2	3	4

5.The Seattle Angina Questionnaire (SAQ)

Research Number: Date completed.....

Q1 - The Seattle Angina Questionnaire

1. The following is a list of activities that people often do during the week. Although for some people with several medical problems it is difficult to determine what it is that limits them, please go over the activities listed below and indicate how much limitation you have had **due to chest pain, chest tightness or angina over the past 4 weeks.**

Place a tick in one box on each line

(Scale 1: Physical limitation scale)

Activity	Severely limited	Moderately limited	Somewhat limited	A little limited	Not limited	Limited or did not do for other reasons
Dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking indoors on level ground	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Showering	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing a hill or a flight of stairs without stopping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Gardening, vacuuming or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking more than a block at a brisk pace	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Running or jogging	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lifting or moving heavy objects (e.g. furniture, children)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participating in strenuous sports (e.g. swimming, tennis)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(Scale 2: Anginal stability scale)

2. **Compared with 4 weeks ago**, how often do you have **chest pain, chest tightness, or angina** when doing your **most strenuous** level of activity?

I have **chest pain, chest tightness or angina...**

Much more often	Slightly more often	About the same	Slightly less often	Much less often
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(Scale 3: Anginal frequency scale – questions 3 and 4)

3. **Over the past 4 weeks**, on average, how many times have you had **chest pain, chest tightness or angina**?

I have **chest pain, chest tightness or angina**...

4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. **Over the past 4 weeks**, on average, how many times have you had to take nitros (nitroglycerin tablets) for your **chest pain, chest tightness or angina**?

I take nitros...

4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(Scale 4: Treatment satisfaction scale – questions 5, 6, 7 and 8)

5. How bothersome is it for you to take your pills for **chest pain, chest tightness or angina** as prescribed?

Very bothersome	Moderately bothersome	Somewhat bothersome	A little bothersome	Not bothersome at all	My doctor has not prescribed pills
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. How satisfied are you that everything possible is being done to treat your **chest pain, chest tightness or angina**?

Not satisfied at all	Mostly dissatisfied	Somewhat dissatisfied	Mostly satisfied	Highly satisfied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. How satisfied are you with the explanations your doctor has given you about your **chest pain, chest tightness or angina**?

Not satisfied at all	Mostly dissatisfied	Somewhat dissatisfied	Mostly satisfied	Highly satisfied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. Overall, how satisfied are you with the current treatment of your **chest pain, chest tightness or angina**?

Not satisfied at all	Mostly dissatisfied	Somewhat dissatisfied	Mostly satisfied	Highly satisfied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(Scale 5: Disease perception scale questions – 9, 10 and 11)

9. Over the past 4 weeks, how much has your **chest pain, chest tightness or angina** interfered with your enjoyment of life?

It has severely limited my enjoyment of life	It has moderately limited my enjoyment of life	It has slightly limited my enjoyment of life	It has barely limited my enjoyment of life	It has not limited my enjoyment of life
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. If you had to spend the rest of your life with your **chest pain, chest tightness or angina** the way it is now, how would you feel about this?

Not satisfied at all	Mostly dissatisfied	Somewhat dissatisfied	Mostly satisfied	Highly satisfied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. How often do you worry that you may have a heart attack or die suddenly?

I can't stop worrying about it	I often think or worry about it	I occasionally worry about it	I rarely think or worry about it	I never think or worry about it
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6-Facet Mindfulness Questionnaire

Research Number: Date completed.....

Please rate each of the following statements using the scale provided. Write the number in the blank that best describes your own opinion of what is generally true for you.

1	2	3	4	5
never or very rarely true	rarely true	sometimes true	often true	very often or always true

- _____ 1. When I'm walking, I deliberately notice the sensations of my body moving.
- _____ 2. I'm good at finding words to describe my feelings.
- _____ 3. I criticize myself for having irrational or inappropriate emotions.
- _____ 4. I perceive my feelings and emotions without having to react to them.
- _____ 5. When I do things, my mind wanders off and I'm easily distracted.
- _____ 6. When I take a shower or bath, I stay alert to the sensations of water on my body.
- _____ 7. I can easily put my beliefs, opinions, and expectations into words.
- _____ 8. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.
- _____ 9. I watch my feelings without getting lost in them.
- _____ 10. I tell myself I shouldn't be feeling the way I'm feeling.
- _____ 11. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.
- _____ 12. It's hard for me to find the words to describe what I'm thinking.
- _____ 13. I am easily distracted.
- _____ 14. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.
- _____ 15. I pay attention to sensations, such as the wind in my hair or sun on my face.
- _____ 16. I have trouble thinking of the right words to express how I feel about things
- _____ 17. I make judgments about whether my thoughts are good or bad.
- _____ 18. I find it difficult to stay focused on what's happening in the present.
- _____ 19. When I have distressing thoughts or images, I "step back" and am aware of the thought or image without getting taken over by it.
- _____ 20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.
- _____ 21. In difficult situations, I can pause without immediately reacting.
- _____ 22. When I have a sensation in my body, it's difficult for me to describe it because I can't find the right words.
- _____ 23. It seems I am "running on automatic" without much awareness of what I'm doing.
- _____ 24. When I have distressing thoughts or images, I feel calm soon after.
- _____ 25. I tell myself that I shouldn't be thinking the way I'm thinking.
- _____ 26. I notice the smells and aromas of things.
- _____ 27. Even when I'm feeling terribly upset, I can find a way to put it into words.
- _____ 28. I rush through activities without being really attentive to them.
- _____ 29. When I have distressing thoughts or images I am able just to notice them without reacting.

- _____ 30. I think some of my emotions are bad or inappropriate and I shouldn't feel them.
- _____ 31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow
- _____ 32. My natural tendency is to put my experiences into words.
- _____ 33. When I have distressing thoughts or images, I just notice them and let them go.
- _____ 34. I do jobs or tasks automatically without being aware of what I'm doing.
- _____ 35. When I have distressing thoughts or images, I judge myself as good or bad, depending what the thought/image is about.
- _____ 36. I pay attention to how my emotions affect my thoughts and behavior.
- _____ 37. I can usually describe how I feel at the moment in considerable detail.
- _____ 38. I find myself doing things without paying attention.
- _____ 39. I disapprove of myself when I have irrational ideas.

7. Self-Compassion Scale

Research Number: Date completed.....

HOW I TYPICALLY ACT TOWARDS MYSELF IN DIFFICULT TIMES

Please read each statement carefully before answering. To the right of each item, indicate how often you behave in the stated manner, using the following scale:

Almost never 1	2	3	4	Almost always 5
----------------------	---	---	---	-----------------------

1	I'm disapproving and judgmental about my own flaws and inadequacies.	
2	When I'm feeling down I tend to obsess and fixate on everything that's wrong.	
3	When things are going badly for me, I see the difficulties as part of life that everyone goes through.	
4	When I think about my inadequacies, it tends to make me feel more separate and cut off from the rest of the world.	
5	I try to be loving towards myself when I'm feeling emotional pain.	
6	When I fail at something important to me I become consumed by feelings of inadequacy.	
7	When I'm down, I remind myself that there are lots of other people in the world feeling like I am.	
8	When times are really difficult, I tend to be tough on myself.	
9	When something upsets me I try to keep my emotions in balance	
10	When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.	
11	I'm intolerant and impatient towards those aspects of my personality I don't like.	
12	When I'm going through a very hard time, I give myself the caring and tenderness I need	
13	When I'm feeling down, I tend to feel like most other people are probably happier than I am.	
14	When something painful happens I try to take a balanced view of the situation.	
15	I try to see my failings as part of the human condition	
16	When I see aspects of myself that I don't like, I get down on myself.	
17	When I fail at something important to me I try to keep things in perspective	
18	When I'm really struggling, I tend to feel like other people must be having an easier time of it.	
19	I'm kind to myself when I'm experiencing suffering.	
20	When something upsets me I get carried away with my feelings	
21	I can be a bit cold-hearted towards myself when I'm experiencing suffering.	
22	When I'm feeling down I try to approach my feelings with curiosity and openness.	
23	I'm tolerant of my own flaws and inadequacies.	
24	When something painful happens I tend to blow the incident out of proportion.	
25	When I fail at something that's important to me, I tend to feel alone in my failure.	
26	I try to be understanding and patient towards those aspects of my personality I don't like.	

8.ILLNESS PERCEPTION QUESTIONNAIRE (IPQ-R)

Research Number: Date completed.....

We are interested in your own personal views of how you now see your current illness (heart condition or stroke or hypertension)

Please indicate how much you agree or disagree with the following statements about your illness by ticking the appropriate box.

	VIEWS ABOUT YOUR ILLNESS	STRON GLY	DISAGR EE	NEITHE R	AGRE E	STR ONG
IP1	My illness will last a short time					
IP2	My illness is likely to be permanent rather					
IP3	My illness will last for a long time					
IP4	This illness will pass quickly					
IP5	I expect to have this illness for the rest of my life					
IP6	My illness is a serious condition					
IP7	My illness has major consequences on my life					
IP8	My illness does not have much effect on my life					
IP9	My illness strongly affects the way others see me					
IP10	My illness has serious financial consequences					
IP11	My illness causes difficulties for those who are close to me					
IP12	There is a lot which I can do to control my symptoms					
IP13	What I do can determine whether my illness gets better or worse					
IP14	The course of my illness depends on me					
IP15	Nothing I do will affect my illness					
IP16	I have the power to influence my illness					
IP17	My actions will have no affect on the outcome of my illness					
IP18	My illness will improve in time					
IP19	There is very little that can be done to improve my illness					

9- Rand-36 (Health Survey)

Research Number: Date completed.....

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

1. In general, would you say your health is:

- ☐ Excellent
- ☐ Very good
- ☐ Good
- ☐ Fair
- ☐ Poor

2. Compared to one year ago, how would you rate your health in general now?

- ☐ Much better now than a year ago
- ☐ Somewhat better now than a year ago
- ☐ About the same as one year ago
- ☐ Somewhat worse now than one year ago
- ☐ Much worse now than one year ago

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?**a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.**

- ☐ Yes, limited a lot.
- ☐ Yes, limited a little.
- ☐ No, not limited at all.

b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?

- ☐ Yes, limited a lot.
- ☐ Yes, limited a little.
- ☐ No, not limited at all.

c. Lifting or carrying groceries.

- ☐ Yes, limited a lot.
- ☐ Yes, limited a little.
- ☐ No, not limited at all.

d. Climbing several flights of stairs.

- ☐ Yes, limited a lot.
- ☐ Yes, limited a little.
- ☐ No, not limited at all.

e. Climbing one flight of stairs.

- ☐ Yes, limited a lot.

9- Rand-36 Health Survey (cont.)

☐ Yes, limited a little.

☐ No, not limited at all.

f. Bending, kneeling or stooping.

☐ Yes, limited a lot.

☐ Yes, limited a little.

☐ No, not limited at all

g. Walking more than one mile.

☐ Yes, limited a lot.

☐ Yes, limited little.

☐ No, not limited at all.

h. Walking several blocks.

☐ Yes, limited a lot.

☐ Yes, limited a little.

☐ No, not limited at all.

i. Walking one block.

☐ Yes, limited a lot.

☐ Yes, limited a little.

☐ No, not limited at all.

j. Bathing or dressing yourself.

☐ Yes, limited a lot.

☐ Yes, limited a little.

☐ No, not limited at all.

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?**a. Cut down the amount of time you spent on work or other activities?**

☐ Yes

☐ No

b. Accomplished less than you would like?

☐ Yes

☐ No

c. Were limited in the kind of work or other activities

☐ Yes

☐ No

d. Had difficulty performing the work or other activities (for example, it took extra time)

☐ Yes

☐ No

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**a. Cut down the amount of time you spent on work or other activities?**

☐ Yes

☐ No

9- Rand-36 Health Survey (cont.)**b. Accomplished less than you would like**☐ Yes ☐ No**c. Didn't do work or other activities as carefully as usual**☐ Yes ☐ No**6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?**

- ☐ Not at all
- ☐ Slightly
- ☐ Moderately
- ☐ Quite a bit
- ☐ Extremely

7. How much bodily pain have you had during the past 4 weeks?

- ☐ Not at all
- ☐ Slightly
- ☐ Moderately
- ☐ Quite a bit
- ☐ Extremely

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- ☐ Not at all
- ☐ Slightly
- ☐ Moderately
- ☐ Quite a bit
- ☐ Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.**a. Did you feel full of pep?**

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

b. have you been a very nervous person?

9- Rand-36 Health Survey (cont.)

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

c. have you felt so down in the dumps nothing could cheer you up?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

d. have you felt calm and peaceful?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

e. did you have a lot of energy?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

**f. have you felt
downhearted and blue?**

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

g. did you feel worn out?

- ☐ All of the time
- ☐ Most of the time

9- Rand-36 Health Survey (cont.)

- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time.

h. have you been a happy person?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

i. did you feel tired?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

- ☐ All of the time
- ☐ Most of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

11. How TRUE or FALSE is each of the following statements for you/

a. I seem to get sick a little easier than other people

- ☐ Definitely true
- ☐ Mostly true
- ☐ Don't know
- ☐ Mostly false
- ☐ Definitely false

b. I am as healthy as anybody I know

- ☐ Definitely true

9- Rand-36 Health Survey (cont.)

- ☐ Mostly true
- ☐ Don't know
- ☐ Mostly false
- ☐ Definitely false

c. I expect my health to get**worse**

- ☐ Definitely true
- ☐ ☐ Mostly true
- ☐ Don't know
- ☐ Mostly false
- ☐ Definitely false

d. My health is excellent

- ☐ Definitely true
- ☐ Mostly true ☐
- ☐ Don't know
- ☐ Mostly false
- ☐ Definitely false.

10. Positive and Negative affect (PANAS)

Research Number: Date completed.....

This scale consists of a number of words that describe different feelings and emotions. Read each item and then mark the appropriate answer in the space next to that word. Indicate to what extent you have felt like this in the past few hours. Use the following scale to record your answers.

Very slightly or not at all	a little	moderately	quite a bit	extremely
1	2	3	4	5

Interested	_____	Irritable	_____
Distressed	_____	Alert	_____
Excited	_____	Ashamed	_____
Upset	_____	Inspired	_____
Strong	_____	Nervous	_____
Guilty	_____	Determined	_____
Scared	_____	Attentive	_____
Hostile	_____	Jittery	_____
Enthusiastic	_____	Active	_____
Proud	_____	Afraid	_____

11. Blood Pressure Readings

Research number:	Baseline assessment	End of group	F/UP
Left SYS			
Left DIA			
PULSE			
NOTES:			

Appendix J

Mindfulness-based Interventions: Teaching Assessment Criteria (MBI: TAC)

Domain	Key features (use following pages to offer qualitative feedback)	Incompetent 1	Beginner 2	Advanced Beginner 3	Competent 4	Proficient 5	Advanced 6
Coverage, pacing and organisation of session curriculum	Adherence to curriculum; Responsiveness and flexibility in adhering; Appropriateness of themes and content; Organisation of teacher, room and materials; Session flow and pacing						
Relational skills	Authenticity and potency; Connection and acceptance; compassion and warmth; Curiosity and respect, Mutuality						
Embodiment of mindfulness	Present moment focus Present moment responsiveness Calm and alertness Attitudinal foundations Person of the teacher						
Guiding mindfulness practices	Language - precise and spacious Key learning for each practice available Elements to consider when guiding						
Conveying course	themes through interactive inquiry and didactic teaching Experiential focus Layers within the inquiry process Conveying learning Teaching skills Fluency						
Holding of group	learning environment Learning container Group development Common humanity Leadership style						

Appendix K

HeLM Acceptability Interview

HeLM end of group interview (MBCT-HeLM only/ completers)

General questions

1. How would you describe your experience of the study?
2. What made you decide to enquire about the trial?
3. What were your expectations of the trial?
4. What was it that made you originally decide to take part in the mindfulness trial for heart conditions/stroke?

View of orientation session

5. I would like you to think back to your initial meeting with the therapist. What were your impressions about that session? Was there anything helpful /unhelpful about it?
6. What did you think about the group after attending the session?
7. What were your expectations for what the course might cover? How did you feel about this following the meeting?

View of group sessions

8. What did you hope to get from attending the group?
9. How do you feel about this now?
10. And once the group started how engaged do you feel you were with the group?
11. Did this change at all during the course?
12. Which techniques used in the course have you found helpful?
13. Which techniques used in the course have you found unhelpful
14. What would you change about the course?

Home practice, location length of course and group

15. How did you find the weekly homework?
16. How engaged were you with the homework?
17. What would you change about the weekly homework?
18. How did you find the questionnaires and assessments throughout the study?
19. What do you think about the length of the course?"
20. What do you think about the design of course (group therapy)?
21. How convenient was the group location for you, parking?
22. What would make it more convenient for you?
23. Did you encounter any challenges in doing the course?

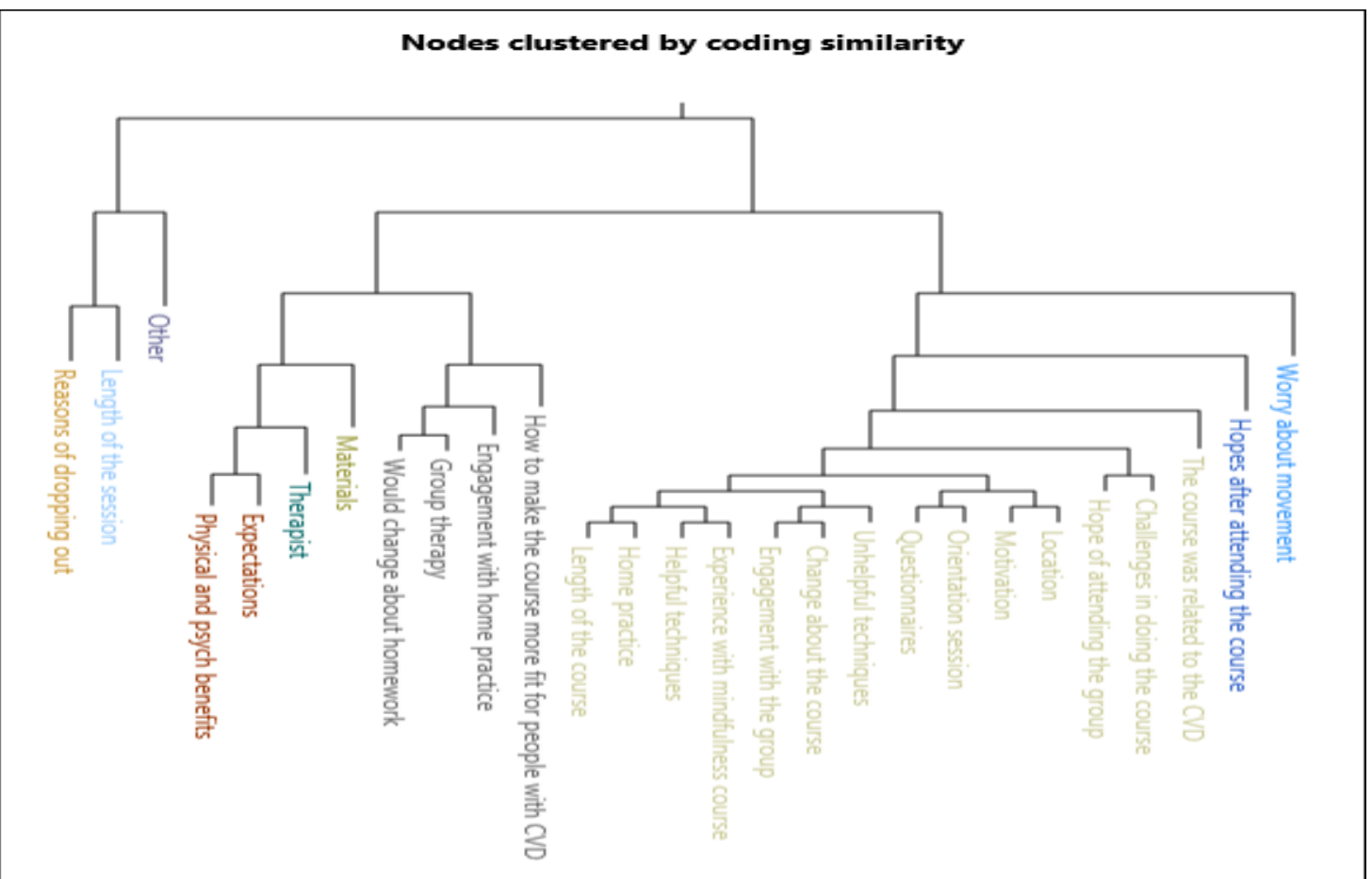
I've covered all of the questions I have, but before I end, is there anything you would like to add?"

Thank you very much

Appendix L

Nodes compared by number of items coded





HeLM Feasibility RCT ethics documents



Bristol Research Ethics Committee Centre
Level 3, Block B, Whitefriars Lewin Mead
Bristol, BS1 2NT, 17 April 2014

Dear Mrs Alsubaie

Study title:	Feasibility and Acceptability of Mindfulness-based Cognitive Therapy in depressed people with vascular disorders: A randomized controlled trial.
REC reference:	14/SW/0048
IRAS project ID:	146763

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Miss Georgina Castledine, nrescommittee.southwest-cornwall-plymouth@nhs.net.

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

HeLM Feasibility RCT ethics documents (cont.)

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

HeLM Feasibility RCT ethics documents (cont.)

Approved documents

<i>Document</i>	<i>Version</i>	<i>Date</i>
Advertisement	1	07 February 2014
Covering Letter		
Evidence of insurance or indemnity		19 July 2013
GP/Consultant Information Sheets	1	14 February 2014
Interview Schedules/Topic Guides	1 - Screening Form	07 February 2014
Interview Schedules/Topic Guides	1 - End of group interview	14 February 2014
Investigator CV		14 February 2014
Letter from Sponsor		22 February 2014
Letter of invitation to participant	1	07 February 2014
Other: FFMQ		
Other: SCS		
Participant Consent Form	1	27 January 2014
Participant Information Sheet	1	07 February 2014
Participant Information Sheet	1.1	07 April 2014
Protocol	1	27 January 2014
Protocol	1.1	02 April 2014
Questionnaire: PHQ-9		
Questionnaire: GAD-7		
Questionnaire: CAQ		
Questionnaire: SF-36		
Questionnaire: SAQ		
Questionnaire: IPQ-R		
Questionnaire: PANAS		
Questionnaire: AD-SUS		
Questionnaire: PHQ-9		
REC application		25 February 2014
Response to Request for Further Information		15 April 2014

The final list of documents reviewed and approved by the Committee is as follows:

HeLM Feasibility RCT ethics documents (cont.)

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “*After ethical review – guidance for researchers*” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

14/SW/0048

Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project.

Yours sincerely




Canon Ian Ainsworth-Smith Chair

Email: nrescommittee.southwest-cornwall-plymouth@nhs.net

Enclosures: “After ethical review – guidance for researchers” [\[SL-AR2\]](#)

Copy to: *Ms Gail Seymour*
Ms Rhianne Lewis, Network Research Facilitator

2. R and D approval

<p>Mrs Modi ALSubaie PhD Student Mood Disorder Centre Washington Singer Laboratories University of Exeter EX4 4QG</p>	<p>Royal Devon and Exeter  NHS Foundation Trust</p> <p>Royal Devon and Exeter Hospital (Wonford) Barrack Road Exeter EX2 5DW</p> <p>Tel: 01392 411611 RESEARCH AND DEVELOPMENT DIRECTORATE Direct Dial: 01392 406933 Direct Fax: 01392 403012 Email: rde-tr.Research@nhs.net Ref: VL/MC/R&D/CG</p>
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6 June 2014

Dear Modi

Study Title: Feasibility and Acceptability of Mindfulness-based Cognitive Therapy in depressed people with vascular disorders: A randomized controlled trial

Researcher Name: Mrs Modi ALSubaie

MREC Ref: 14/SW/0048

Thank you for submitting your study documents to the Royal Devon & Exeter NHS Foundation Trust for review. We can confirm that the research satisfies our checks and has the following:

- Ethics Approval
- Sponsorship
- Research protocol
- Participant Information Sheet and Consent
- CVs for research team

This assurance is for research based on the documents provided by the researcher and does not take into account any alterations to the research after the date of this letter.

Research Governance

I would like to take this opportunity to remind you of your responsibilities as a Principal Investigator. These are:

1. Research procedures must be carried out in line with Good Clinical Practice and the Research Governance Framework for Health and Social Services, which details the responsibilities for everyone involved in research.
2. The Data Protection Act 1998 requires you to follow the eight principles of 'good information handling'.
3. To provide information when requested for research governance monitoring and auditing purposes.
4. You must be aware of, and comply with, Health and Safety standards in relation to your research.

Research Assurance Letter
V2.0 15/04/13


Chairman: James Brent Chief Executive: Angela Pedder OBE

WZK856

This letter is not an approval letter for the research to take place, but provides assurance that the study has been reviewed and has been approved by ethics.

It is advised that you, as the researcher, obtain written approval from each GP practice you wish to involve in your study.

Yours sincerely


Chris Gardner
R&D Directorate Manager

HeLM Feasibility RCT ethics documents (cont.)

3.GPs Letter to potential participants

<p>Surgery Header/Logo</p> <p>Surgery address, phone, names of GPs</p> <p style="text-align: right;">Date as postmark</p>
<p>Dear Name of Patient</p> <p>Referral to Heart and Living Mindfully (HeLM) Research Study</p> <p>I would like you to consider taking part in a therapy research trial that is looking to see if a new course of Mindfulness-based Cognitive Therapy (MBCT) can help people with vascular disorders (heart disease or stroke) and low mood to manage their physical and mental well-being. This letter has been sent to you because in the past you have experienced some form of heart disease or had a stroke. We have decided to send this letter to everyone on our records in this situation as we know it can be common for people who have experienced these things to also suffer from low mood. However, if you do not feel this applies to you please ignore this letter.</p> <p>You can find out more about this study from the Patient Summary Pamphlet which I've included with this letter. Please read this carefully and think about whether or not you would like to take part in the study. If you have any questions you would like to ask, you can talk to me or to Modi Alsubaie, the Lead Researcher (tel. 01392 726101).</p> <p>If you would like to be considered for this therapy research trial then you can contact the research team on 01392 726101, or by returning the enclosed ready prepared letter, or emailing msfa202@exeter.ac.uk to discuss this further.</p> <p>I would like to reassure you that the details of your personal medical records will always remain confidential within this GP practice care team.</p> <p>Thank you for taking the time to read this letter.</p> <p style="margin-top: 20px;">Yours sincerely,</p> <p style="margin-top: 20px;">GP name</p>

HeLM Feasibility RCT ethics documents (cont.)

4. Letters from HeLM team to participants

First Screen Letter



Private & Confidential

Dear

Re: Mindfulness-based Cognitive Therapy Group for Heart Conditions - HeLM

Thank you for taking the time to speak to me regarding our study. As I said on the phone we will contact you again in October to discuss the study further and to ask you some more questions. It is at this point that we will then invite you in to meet with our researcher for your initial assessment. This assessment will confirm that you are eligible to take part and that the study is right for you.

Please find enclosed a full information booklet about the study; please ensure you read this to ensure you are happy with the information and are interested to take part.

In the meantime, if you wish to speak to us at any point please do not hesitate to contact us 01392 726101. If you leave a message, we will get back to you.

Best wishes,

Modi Alsubaie
Researcher

Supervised by
Willem Kuyken, Professor of Clinical Psychology.
Chris Dickens, Professor of Psychological Medicine.

HeLM Feasibility RCT ethics documents (cont.)

5. Baseline Letter



Private & Confidential

October 2014

Letters to control group

Dear

Re: Mindfulness-based Cognitive therapy for people with cardiovascular disorders.

Thank you very much for taking part in HeLM project as member of control group. We would like to invite you to an assessment session at university of Exeter that will take 40 mins and includes completing the same questionnaires that you have completed last November. Alternatively, we can send you the questionnaires to complete at home.

As promised, we offer you a mindfulness course that you could join in once we finish the last assessment in June 2015. This year, we have two mindfulness courses. The first one will be held end of June and the second will be end of September and you are welcome to take part in any of them.

I've enclosed with this letter a form to fill it out regarding your availability to meet me for the assessment and your preferences regarding the mindfulness group that you would like to take part. There is a prepaid envelope that you can use to send the form back to me.

Thank you very much.

I look forward to hearing from you.

Yours sincerely,

Modi Alsubaie
Researcher

Supervised by
Willem Kuyken, Professor of Clinical Psychology and Chris Dickens, Professor of Psychological Medicine.

HeLM Feasibility RCT ethics documents (cont.)

6. Letter from HeLM team to GPs



Private & Confidential

Re: Patient name and address

HeLM: Mindfulness-based Cognitive Therapy for cardiovascular Disorders

Dear Dr ...

I am writing to inform you that the above patient will be participating in our study examining whether a new course of Mindfulness-based Cognitive therapy can help people with vascular disorders to manage their physical and mental well-being.

For any questions regarding your patient's participation in the study or the study itself, please contact me on xxxxxxxxxxxx.

Best regards,

Researcher

HeLM Feasibility RCT documents (cont.)

7. Reply Form

Heart and Living Mindfully (HeLM)

Thank you for taking the time to read the brief information about the HeLM study. We appreciate that this is a short summary of the study and you may want more information to make an informed choice. If you would like to find out more then please fill out the slip below. If you are not sure feel free to hold onto it until you have decided and contact us via the details below;

- Email: msfa202@exeter.ac.uk
- Telephone: 01392 726101

I am interested in finding out more about the study

I confirm that I have read the information provided and would like to be contacted to discuss it further. I understand that my participation is voluntary and that I am free to withdraw at any time.

Name: _____

Address: _____

Preferred telephone numbers: _____

It is OK to leave an answer phone message on this number? YES / NO

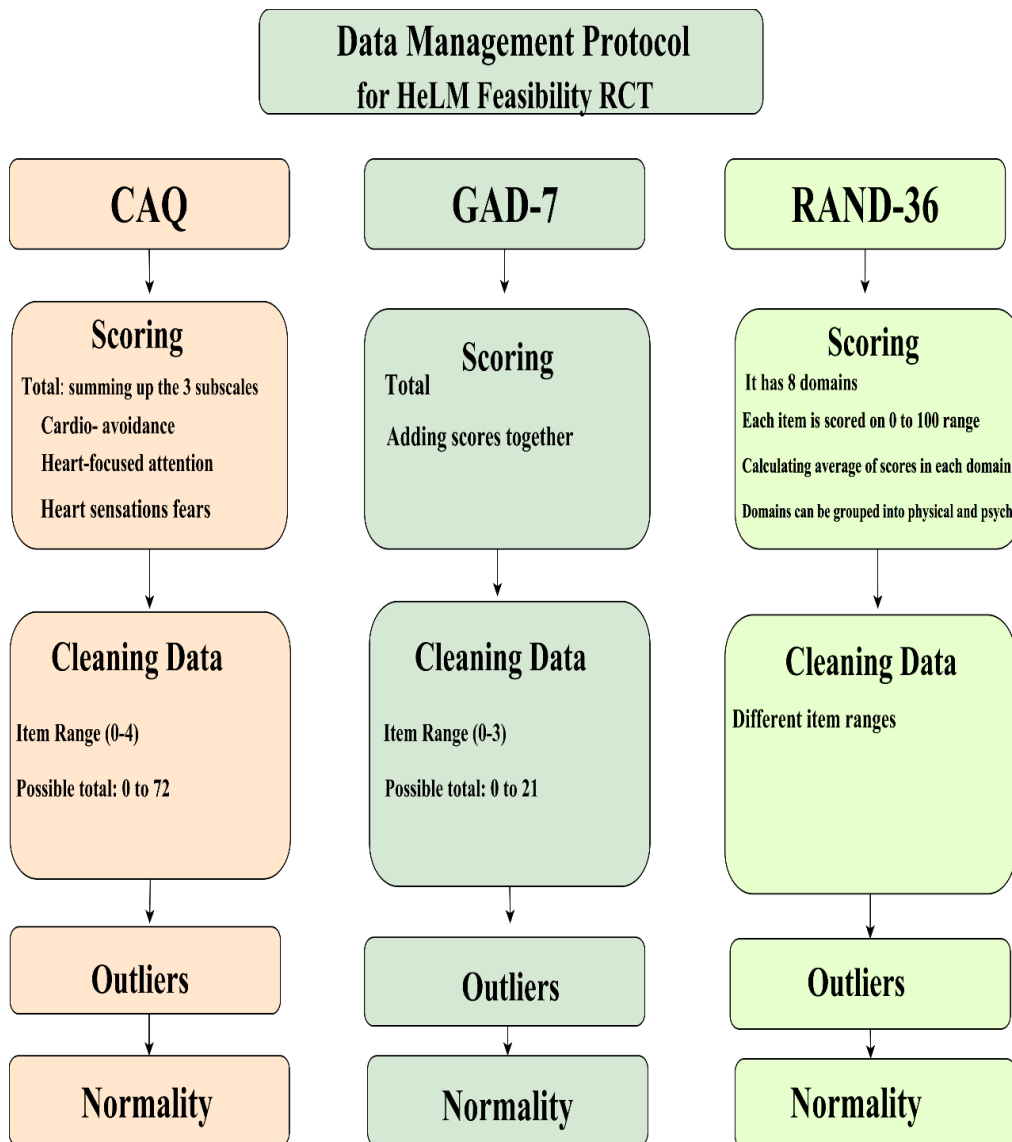
Email address (optional): _____

When is the best time to call?: _____

I am not interested in finding out more about the study, thank you. ☐

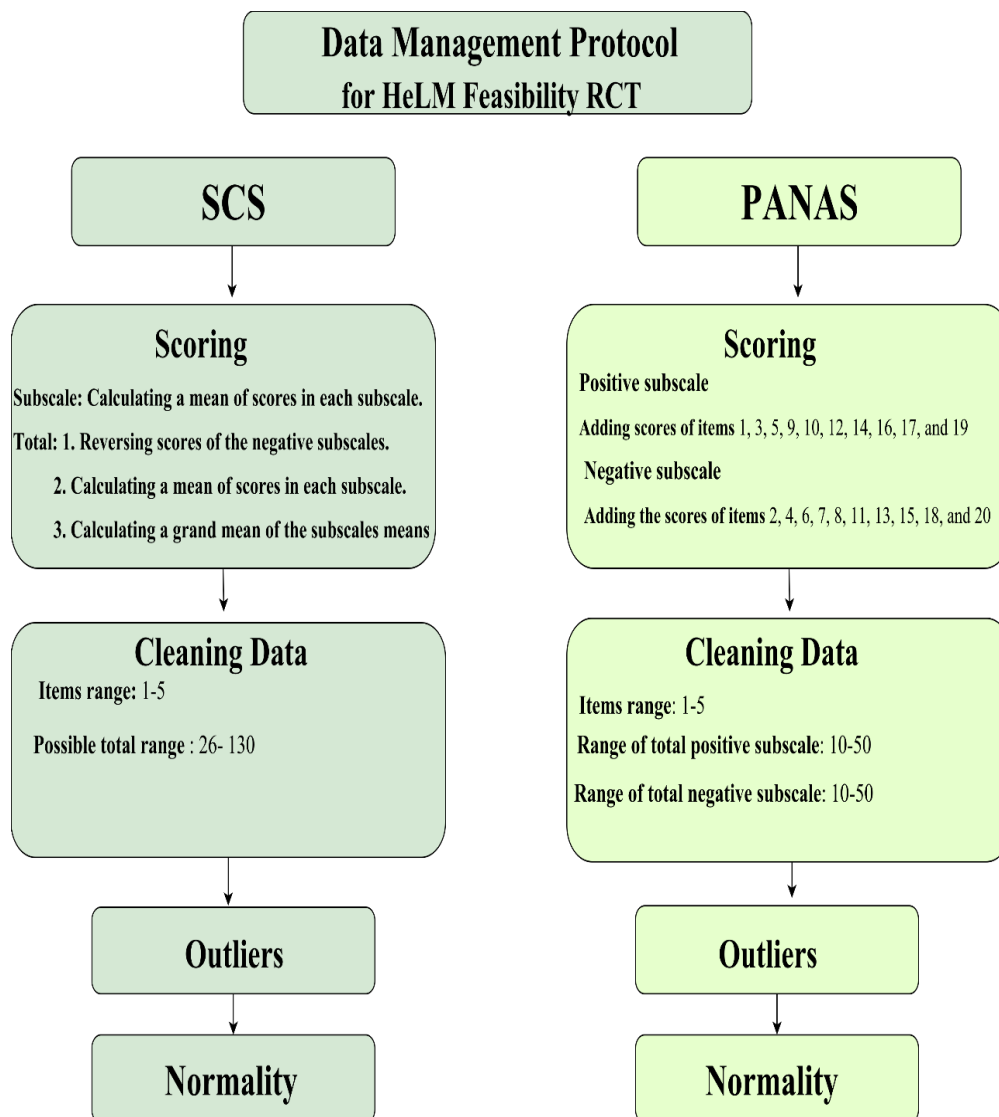
HeLM Feasibility RCT documents (cont.)

8.Data Management Protocol for HeLM Feasibility RCT



HeLM Feasibility RCT documents (cont.)

8.Data Management Protocol for HeLM Feasibility RCT (cont.)



HeLM Feasibility RCT documents (cont.)

9.MBCT-HeLM Manual

Session Outlines

Orientation Session

THEME

The initial orientation with the MBCT teacher is a starting point for dialogue between the MBCT participant and teacher. Forming a therapeutic relationship with each participant and orienting him/her to the rationale for and practicalities of MBCT and certain aspects of the trial are likely to enable full participation. It also enables instructors to facilitate enquiry in the groups individualised to some degree to individual's particular history and goals.

AGENDA

After reading questionnaires

- Learn about the factors that have been associated with the onset and maintenance of long-term physical and mental health problems (using client terminology), including the way the person's physical health has affected their mental health and vice versa. How does it (client terminology for physical health problem) affect your life? How does it affect your mood / spirits / relationships?
- Learn about the beliefs and resources that the person has developed in coping with his / her physical and mental health problems to date and reasons for attending.
- Clarify participants' expectations
- Introduce the road-block and oxygen mask metaphors
- Introduce the idea symptoms as guides from the body and how mindfulness and self-care are ways of hearing and responding to these messages.
- Explain something of the background and aims of MBCT.
 - To help people who have suffered physical and mental health problems learn skills to help manage their symptoms and emotions.
 - To become more aware of bodily sensations, symptoms, concerns, feelings, and thoughts, from moment to moment
 - To help participants learn different ways of relating to physical symptoms, sensations, thoughts, feelings, situations, – specifically, mindful acceptance and acknowledgement of unwanted feelings and thoughts, rather than habitual, automatic, pre-programmed routines that tend to perpetuate difficulties, moving to a more responsive rather than reactive place
 - Reacquainting with the body in a more positive way
 - Individualised formulation and way that the practice may need to be adapted.
 - To help participants to be able to choose the most skilful response to any unpleasant thoughts, feelings, physical symptoms or situations that they meet.
 - To develop an integrated approach to care
 - To learn from others with similar experiences
- Outline structure of the MBCT programme
 - Groups of 8-12
 - Eight weekly 2 hour 15min sessions

9.MBCT-HeLM Manual (cont.)**Orientation Session (cont.)**

- Home Practice
 - Video recording and consent sheet
 - Involvement of other health care professionals
- Emphasize that MBCT will involve hard work, commitment and a need for patience and persistence in that work, over the course of the 8 weeks.

PLANNING AND PREPARATION

- In addition to your personal preparation before the meeting, remember to familiarise yourself with any background information about the person's presentation

9.MBCT-HeLM Manual (cont.)

Session 1: AUTOMATIC PILOT

THEME

On automatic pilot, it is easy to drift unawares into “doing” mode and the automatic reactions and ruminative/worry thought patterns that can feed old unproductive patterns of thinking and behaving. Habitual doing mode also robs us of our potential for living life more fully. We can transform our experience by intentionally paying attention to it in particular ways. We begin to practice stepping out of automatic pilot by paying attention intentionally, mindfully, to eating, to the sensations of the body, and to aspects of everyday experience.

AGENDA

- Establish the orientation of the class
 - Honour the commitment everyone has made
 - Set the ground rules regarding confidentiality, participation and time keeping, ease and comfort in the body. Creating a safe place to work.
- A short reflective practice coming to the body and then dropping in a question about intentions for being here. Ask participants to pair up and introduce themselves to each other, then to the group as a whole, giving their first names and, what they hope to get out of the program and very briefly an outline of their heart/vascular condition and their mood/stress.
- Short movement either sitting or standing as a way of coming into the body
- The raisin exercise
- Feedback and discussion of the raisin exercise
- Body scan practice (with some guidance on posture and ways of sitting/lying) – starting with the short breath focus including some focus on the sensations around the heart area. Focus on what is right. Feedback and discussion of body scan
- Home Practice: Discuss and assign for the coming week
 - Body scan
 - Mindfulness of a routine activity
 - Mindfulness of eating
- Distribute CDs and session 1 participant handouts
- Discuss in pairs:
 - Timing for home practice
 - What obstacles may arise
 - How to deal with them
- End the class with a short breath focus
-

PLANNING AND PREPARATION

- Bowl with raisins and a spoon
- CD body scan
- Copies of participants’ folders for the programme.
- Flip chart and pens
- Handouts
- Bell

9.MBCT-HeLM Manual (cont.)

Guidelines for MBCT Group.

Housekeeping

Toilets, mobile phones off, fire, bell, chimes/bowl, tea/coffee, video

Ground rules

Time-Keeping

- I aim to start and finish on time.
- From now on, each session begins with period of practice so if you do happen to be late, I will always have a chair or mat out for you, just coming in quietly and join in practice when you're ready.

Attendance

- Each session a **significant building block** to the whole so important to try and attend all.
- **But just say you have to miss one** then I'd really appreciate it if you could let me know in advance by phone or email. **And we will miss you if you're not here...**
- **And you don't need to be a certain way to come along** – you don't need to come with a smiling face!

Confidentiality – does anyone know each other here?

- Important that we create a safe place where we can share and learn from each other..... Might be tempting to go home and share what's happening in the group with friends or family and what I would like to suggest is that **it's fine to talk about your own experience or the group in general terms but not to mention any names or speak of anyone else's experience.**
- And if you're out and about and you happen to bump into someone from the group and they're with someone else just to be sensitive to the fact that they may not want to be spoken to....

Participation/Sharing

- We're not here to go over the past or the content of one's problems but seeing instead if we can work more helpfully with our patterns of mind and body **in the moment** – so there may be times when I might **invite us all to pause** if I notice we're getting caught up in lots of thoughts and come back to what's happening now.
- I really **welcome you to share your experiences** from the practices but equally there is really no obligation to share – tuning into what feels right for you...
- **Listening** is as much of an active part of being in a group as speaking...

9.MBCT-HeLM Manual (cont.)

Commitment

- **The sessions but particular the home practice can feel** intense, difficult, You will not necessarily enjoy it – it will feel challenging at times, boredom, impatience etc. may all be feelings that arise. **And this is all part of it – so as best we can letting go of any expectations** about how things should be on this course or ought to be 'just do it and see what happens'

Support out of session

- My number/email address, messages are checked every
- Also available after the group if you need to speak to me.

Open Mind and Heart

- Sometimes it may not be clear how what we're doing links with protecting ourselves from depression but I would just ask you to bring an open mind to each session, each moment...

Gentleness and kindness

Physical needs

- Feel free to stand and stretch and move around the room at any point
- All guidance is an invitation please leave out what doesn't feel right for your body or adjust

9.MBCT-HeLM Manual (cont.)

Session 2: LIVING IN OUR BODIES & HEADS

THEME

In doing mode we “know about” our experience only indirectly, conceptually, through thought. This means we can easily get lost in rumination and worry, and old patterns of reactivity. Mindfulness of the body provides an opportunity to explore a new way knowing directly, intuitively – “experimentally” to the body as it is, rather than how we think it is. Experiential knowing is a way to be aware of unpleasant experiences without getting lost in ruminative thought about the past, worry about the future or thinking about the body. Already, most participants will be experiencing some difficulties in their practice. These difficulties offer precious opportunities to practice letting go of thinking and to connect with direct awareness of the body. Reacquainting ourselves with the body in terms of what is right with the body, appreciating the body. Importance of taking care of ourselves (and the issues this can raise).

AGENDA

- Body Scan Practice (guiding around sensations in the heart area) and review
- Home Practice Review – (including body scan, mindfulness of a routine activity, Mindfulness of eating) weaving in the theme of importance of taking care of ourselves (and the issues this can raise).
- Sensations, Thoughts and Feelings Exercise. "You wake up in the morning and you feel unwell and very tired (but you've got important plans, which also involve other people and you are not sure you can even get out of bed). What do feel, think, experience in your body?
- Ten- minute sitting meditation (with guidance on how to sit in a chair) and review
- Distribute Session 2 participant handouts
- Home Practice assignment:
 - Body Scan CD, 6 out of 7 days
 - 10 minutes mindfulness of breathing daily
 - Pleasant Experiences Calendar (one example daily).
 - Mindfulness of a new routine activity

PLANNING AND PREPARATION

- Flip chart and pens
- Guidelines for the group
- Handouts
- Flip chart and pens
- Bell

9.MBCT-HeLM Manual (cont.)

Session 3: GATHERING THE SCATTERED MIND

THEME

The mind is often scattered and lost in thought because it is working away in the background to complete unfinished tasks and strive for future goals. Instead, we need to find a way to intentionally “come back” to the here and now. The breath and body can offer an ever-present focus on which we can reconnect with mindful presence, gather and settle the mind, and ease ourselves from doing into being. For people for whom the breath and/or particular parts of the body tend to trigger strong aversive reactions another anchor can be found for attention. The focus is on gathering the mind with an identified anchor.

AGENDA

- 5 minutes “seeing” (or “hearing”) exercise.
- 20-minute mindful movement (giving guidance around the heart and breath during the movement) and review.
- Home Practice Review (including body scan, mindfulness of the breath and routine activity)
- Pleasant Experiences Calendar – using the body diagram for the feedback
- 3 Stage Breathing Space and review.
- Short sitting (Breath/Body) and review
- Distribute Session 3 participant handouts.
- Unpleasant Events Calendar.
- Home Practice assignment (in pairs how to fit it in):
 - Short sitting (breath/body) CD on days 1, 3 and 5.
 - Mindful movement CD on days 2, 4, and 6 or continue with Body Scan
 - Unpleasant Experiences Calendar (a different experience connected with vascular disorder daily).
 - 3 Stage Breathing Space, three times daily.

PERSONAL PREPARATION AND PLANNING

- CDs – Movement, Breathing Space, Short Sitting (Breath/Body)
- Handouts
- Bell
- Flip chart and pens

9.MBCT-HeLM Manual (cont.)

Session 4: RECOGNIZING FEAR AND AVERSION

THEME

The skill of “coming back” needs to be complemented by seeing more clearly what “takes us away” into doing, rumination, mind wandering, and worry. We begin the experiential investigation of “aversion”, the mind’s habitual reaction to unpleasant feelings and sensations, driven by the need not to have these experiences, which is at the root of emotional suffering. Aversion is an understandable turning away from experiences that may well be fear-based, but will likely fuel physical and mental symptoms. Taking a different approach requires considerable courage. Mindfulness offers a way of staying present by giving another way to view things. It helps us take a wider perspective and relate differently to experience. For MBCT teachers using the RAIN acronym (Recognise, Allow, Inquire and thoughts are Not facts) can be helpful in teaching and inquiry, with the first stage being recognition when fear and aversion arise.

AGENDA

- 30 Sitting Meditation - awareness of breath, body, sounds, and then thoughts.
- Practice Review.
- Home Practice Review (including short sitting CD alternating with Mindful movement CD, and 3 Stage Breathing Space).
- Unpleasant Experiences Calendar using the Body Diagram in feedback. Introduce 2 darts.
- Automatic thoughts - defining the “territory” of mental and physical health problems
- 3 Stage Breathing Space and review
- Mindful Walking and review
- Review the sequence
- Selected extracts from Healing From Within DVD
- Distribute Session 4 participant handouts.
- Home Practice assignment:
 - Sitting Meditation CD (6 out of 7 days)
 - 3 Stage Breathing Space – Regular (three times a day).
 - 3 Stage Breathing Space – Responsive (whenever you notice unpleasant feelings).
 - Noting Stress Reactions diagram

PERSONAL PREPARATION AND PLANNING

- CD Full Sitting
- Negative Automatic thoughts
- Handouts
- Selected extracts from Healing within DVD
- Bell
- Flip Charts and pens

Session 4**Negative Automatic Thoughts**

My life's not going the way I want it to
What's wrong with me?
I feel like I am up against the world
I don't think I can go on
My future is bleak
My body just doesn't work the way it should / used to
Nothing feels good anymore
I can't stand this anymore
I don't like the way I am
It's just not worth it
The future is scary
People think there is something wrong with me
What will happen to me if I can't look after myself?
I don't fit in
I'm not pulling my weight
Getting help is hard
I am a burden to others
I'm frightened
I can't provide, money is a worry
Is it worth it?
Will it happen again?
Will I be able to look after myself, and if I can't...
Letting people help is hard

9.MBCT-HeLM Manual (cont.)

Session 5: SOFTNESS AND STRENGTH

THEME

Relating differently to unpleasant feelings and sensations – allowing things to be as they already are. We can disempower aversion by intentionally bringing to all experience a sense of “allowing” it to be, just as it is, without judging it or trying to make it different. Such an attitude of acceptance embodies a basic attitude of opening to and “softness” with experience that can be experienced as considerable “strength.” From this clear seeing we can choose what, if anything, needs to change and the beginning of a more empowering approach to self-care. The RAIN acronym progresses here to the A and possibly the I.

AGENDA

- 30-40 minute Sitting Meditation – awareness of breath and body; noticing how we relate to our experiences through the reactions we have to whatever thoughts, feelings or body sensations arise; introducing a difficulty within the practice and noting its effects on the body and reactions to it.
- Practice review.
- Home Practice Review (Sitting Meditation CD, 3 Stage Breathing Space – Regular and Responsive)
- Gathering of the **Noting Stress Reactions** from the week using The Body diagram and linking with the physical barometer Breathing Space (with added instructions) as a “first step” with the option of the body door
- Read The Guest House
- Further extracts from Healing within DVD that speak to allowing and softness and strength
- Distribute Session 5 participant handouts
- Home Practice assignment:
 - Sitting Meditation - on days 1, 3, and 5; use no guided practice on days 2, 4, and 6 instead, but guide yourself through the same meditation.
 - Optional Working with difficulty meditation
 - 3 Stage Breathing Space – Regular (3 times a day).
 - 3 Stage Breathing Space – Added Instructions (whenever you notice unpleasant feelings).

PLANNING AND PREPARATION

- Poem “The Guest House”
- Poster
- Handouts
- CD- working with difficulty
- Bell
- Flip charts and pens

9.MBCT-HeLM Manual (cont.)

Session 6: SYMPTOMS AS MESSAGES FROM THE BODY; THOUGHTS ARE NOT FACTS

THEME

Relating differently to experiences. We free ourselves from the impact of physical symptoms, fear-based thinking/imagery and ruminative doing mode when we clearly see that physical sensations and negative emotions as passing experiences, and negative thinking as the distorted products of those experiences. It is enormously liberating to realise that our thoughts are merely thoughts, even the ones that say they are not, and to recognise the contexts out of which they are born. Similarly, physical symptoms are changing experiences that can be interpreted as messages from the body, to be listened to and responded to, however difficult that may sometimes be. The RAIN acronym progresses here to the Inquiry and thoughts are Not facts.

AGENDA

- 30 -40 minute Sitting Meditation – awareness of breath, body, sounds, thoughts and thoughts / feelings, particularly noticing how we relate to thoughts that arise. Choiceless awareness
- Practice review.
- Home Practice Review (including Sitting Meditation with and without recorded guidance, working with difficulty and breathing spaces).
- Mention preparation for end of course.
- Reacting/responding Exercise: 1. What is the symptom that causes you stress and worry? 2. Imagine it now. Locate it in the body, what are the thoughts and emotions. What are your reactions? (may include a diversity of reactive and responsive) 3. Gather on flip chart using body diagram. 4. Breathing Space. 5. re there any other more compassionate responses?
- Discuss Breathing Space as the “first step” before the thoughts door
- Ways to see thoughts differently – gather ideas from the group
- Discuss Recognising signs and reactions to stress/low mood worksheet
- Distribute Session 6 participant handouts Home Practice assignments:
 - Practice with a selection of guided meditations for a minimum of 30 minutes a day.
 - 3 Stage Breathing Space – Regular (3 times a day).
 - 3 Stage Breathing Space – Responsive (whenever you notice unpleasant feelings).
 - Recognising signs and reactions to stress/low mood worksheet
 -

PLANNING AND PREPARATION

In addition to your personal preparation,

- Handouts
- Bell
- Flip chart and pens

9.MBCT-HeLM Manual (cont.)

Session 7: TAKING CARE OF MYSELF

THEME

Using skilful action to take care of ourselves. We can improve our mental and physical health by intentional skilful action. Developing a personalised self-care plan is a proactive way of doing this. At times of stress, after taking a breathing space, we kindly take care of ourselves by acts that promote health, give pleasure or a sense of mastery.

AGENDA

- 30-40-minute Sitting Meditation – awareness of breath, and body: noticing how we relate to our experiences through the reactions we have to whatever thoughts, feelings, or body sensations arise; especially when difficulties arise within the practice, noting their effects and reactions to them, on the body.
- Practice review.
 - Home Practice Review (Including shorter meditations and breathing spaces)
 - Review of daylong
 - Links between activity and well-being exercise
 - Plan how best to schedule activities for when physical symptoms and mood states threaten to overwhelm
 - Rebalancing nourishing and depleting activities
 - Generating a list of nourishing activities.
- 3 Stage Breathing Space as the “first step” before choosing whether to take mindful action.
- Responding wisely to stress/low mood worksheet- Identifying actions to deal with decreased well-being incorporated with mindful walking. Walking for a short while, stopping, turning to a partner and describing one way you can take care. Continue and repeat 4-5 times.
- Distribute Session 7 participant handouts.
- Home Practice assignment:
 - Select from all the different forms of practice, a pattern you intend to use on a regular basis.
 - 3 Stage Breathing Space – Regular (3 times a day).
 - 3 Stage Breathing Space – Responsive (whenever you notice unpleasant feelings).
 - Complete responding wisely with stress/low mood worksheet
 - Complete questionnaires and feedback form

PLANNING AND PREPARATION

- Poem “Walking down the street”
- Handouts
- Bell
- Flip chart and pens
- Post group questionnaires including feedback questionnaire

9.MBCT-HeLM Manual (cont.)

Session 8: MAINTAINING AND EXTENDING NEW LEARNING

THEME

Planning for a new way of living. Maintaining and extending a more mindful and caring way of being requires clear intention and planning. It is helpful to link intentions for regular mindfulness practice to a personally significant value or positive reason for taking care of oneself.

AGENDA

- Body Scan Practice.
- Brief practice review.
- Home Practice Review (including working wisely with stress/low mood worksheet 2).
- Review whole course: what has been learned – in pairs then go around the whole group.
- Collect questionnaires
- Discuss how best to keep up momentum and discipline developed over the past 7 weeks in self-care and (formal and informal) mindfulness practice.
- Check and discuss plans, and link them to positive reasons for maintaining the practice.
- Distribute Session 8 participant handouts. End the class with a concluding meditation (marble, stone, or bead). Or with participants wishing each other well.

PLANNING AND PREPARATION

In addition to your personal preparation,

- Bell
- Flip chart and pens
- A memento for each participant, to mark the end of the programme, depending on your practice.
- Handouts
- Booklist and resources

Feedback on the Programme and Thinking to the Future

Name:

Think back to why you came originally – what were your expectations and why did you stay?
What did you want / hope for?

What did you get out of coming, if anything? What did you learn?

What were the costs to you? What are your biggest blocks / obstacles to continuing? What strategies might help you not get stuck (in continuing with what you have learned)?

How important has the programme been to you, on a scale of 1 to 10?

1	2	3	4	5	6	7	8	9	10
Not at all important							Extremely important		

Why did you give this rating

